Medication Safety Committee

Apr 08, 2015 at 10:00 AM - 02:00 PM

California Hospital Association

1215 K Street, Suite 800

Sacramento, California 95814

Conference Call Option:

Meeting Book - Medication Safety Committee Meeting

AGENDA

Meeting Facilitator: BJ Bartleson

10:00	**I. CALL TO ORDER/INTRODUCTIONS**		Hanni
	A. Roster/Member Map/Member Geographics		
	i. MSC Roster - Page 5		
	ii. MSC Member Map - Page 9		
	iii. MSC Member Geographic 2015 - Page 10		
	B. Membership Updates		
	i. Member Update Memo - Page 11		
	C. Attendance Roster		
	i. MSC Attendance Roster - Page 12		
	D. Committee Guidelines		
	i. MSC Guidelines - Page 14		
10:15	**II. MINUTES**	*Recommend: Approval*	Hanni/Fong
	A. MSC Draft Minutes 010715 - Page 18		
10:20	**III. OLD BUSINESS**		
	A. Sterile Compounding Regulations/Matrixes Update		Hanni/Herold
	i. CHA Lab Testing Required for Low-Medium Risk Sterile Compounding with USP BUDs_JHREV10132014 - Page 22		
	ii. CHA Pharmacy Temperature Requirements_JH 09092014 - Page 23		
	iii. CHA Sterile Compounding Documentation Frequency_JHREV 10132014 - Page 24		
	iv. CHA Sterile Compounding Grid Recommendations_JH09112014 - Page 25		
	B. Pharmedium		Bartleson/Herold
	C. CDPH AFL 14-34		Hacker/O'Brien
	i. AFL 14-34 - Page 26		
	ii. Implementation of SB 1039 and Program Flex Requests - Page 29		
	iii. CDPH Program Flex Tips - Page 32		
	D. SBAR		Munoz

i. SBAR 011615 - Page 34

E. Generic Drug Pricing — Bartleson

i. CHA Board Report - Generic Drug Price Increases - Page 36

10:50 **IV. NEW BUSINESS**

A. BOP Title 16 — Bartleson

i. Compounding Comment Letter 022015 - Page 37

ii. Compounding Comment Letter 031815 - Page 41

iii. BOP Proposed Action Title 16 - Page 44

iv. BOP Initial Statement of Reasons - Page 56

v. BOP Proposed Language - Page 92

B. FDA - New Draft Guidelines — Hanni/Bartleson

i. FDA Draft Guidance Announcement - Page 94

ii. Draft Guidance - Whether to Register - Page 97

iii. Draft Guidance - Repackaging - Page 105

iv. Draft Guidance - Biologics - Page 118

v. Draft Guidance - Outsourcing Facilities - Page 138

vi. Draft MOU Final - Page 151

C. ISO Small Bore Connectors Issue — Jaffe

i. March 2015 Update - Page 159

D. Drug Cost Increases — Hanni/Bartleson

i. Specialty Drugs High Cost - News Article - Page 210

11:40 **V. STANDING REPORTS**

A. Board of Pharmacy — Herald

B. CDPH — Lee/Woo

C. CSHP — Hacker

D. CALNOC — Foley

E. ACNL

F. CHPSO — Jaffe

G. CAHF — Montgomery

12:00 **VI. LUNCH**

12:30	**VII.**	**WORK GROUP REPORTS**	*Which workgroups have been stopped?*	
		A. High Risk/High Alert (HR/HA) Drugs		Hacker/Benton
		B. ED Management Medication Safety		Bartleson
		C. Drug Shortage		Jaffe
		D. Medication Technology		Jaffe
1:30	**VIII.**	**PHARMACY LEGISLATIVE UPDATES**		Bartleson
		A. Pharmacy Leg Bills April 6, 2015 - Page 215		
		B. Support Letter - AB 486 - Page 223		
1:45	**IX.**	**OTHER BUSINESS**		
		A. San Diego Prescription Drug Abuse Task Force Update		Munoz
		i. Update Report - Page 225		
	X.	**NEXT MEETING**		
		A. 2015 Meeting Schedule - Page 227		
2:00	**XI.**	**ADJOURNMENT**		Hanni

MEDICATION SAFETY COMMITTEE
2015

CHAIR

JEANNETTE HANNI, R.Ph, MPA, FCSHP
Regional Executive Director of Pharmacy Services
Peninsula Coastal Region – Sutter Health
2350 W El Camino Real
Mountain View CA 94040
(650) 696-5694
hannij@sutterhealth.org

CO-CHAIR

CANDACE FONG, Pharm.D
Director of Pharmacy and Medication Safety
Dignity Health
3400 Data Drive
Rancho Cordova, CA 95670
(916) 851-2678
Candace.fong@dignityhealth.org

MEMBERS

EDDIE AVEDIKIAN, PharmD
Pharmacy Operations Manager
Providence Holy Cross Medical Center
15031 Rinaldi Street
Mission Hills, CA 91346-9600
(818) 496-4594
eddie.avedikian@providence.org

DAWN BENTON, MBA
Executive Vice President & CEO
California Society of Health-System Pharmacists
1314 H Street, Suite 200
Sacramento, CA 95814
(916) 447-1033
dawn@cshp.org

NANCY BLAKE, PhD, RN, CCRN, NEA-BC
Director, PCS Critical Care Services
Children's Hospital Los Angeles
4650 Sunset Blvd, Mail Stop #74
Los Angeles, CA 90027
(323) 361-2164
nblake@chla.usc.edu

JACALYNN BLANKENSHIP, BSN, MA, RN
Director of Clinical Practice and Quality
CALNOC
2410 Camino Ramon, Suite 360
San Ramon, CA 94583
(925) 594-1145
jacalynn.blankenship@calnoc.org

CAROLYN BROWN, RN, MS, BC, CNA
Director, Quality and Safety
Santa Clara Valley Medical Center
2325 Enborg Lane, Ste. 340
San Jose, CA 95128
(408) 885-2093
carolyn.brown@hhs.sccgov.org

KATIE CHOY, MS, RN, CNS, NEA-BC
Nursing Director, Education
Washington Hospital Healthcare System
2000 Mowry Avenue
Fremont, CA 94538
(510) 608-1366
choyka@whhs.com

EDNA DELEON, RN, MSN
Director, Quality Management
Huntington Memorial Hospital
100 W. California Blvd
Pasadena, CA 91105
(626) 397-3734
edna.deleon@huntingtonhospital.com

KEVIN DORSEY-TYLER, MD, PhD
Medical Director, Clinical Analytics
Enloe Medical Center
1531 Esplanade
Chico, CA 95969
(530) 891-5266
kevin.dorseytyler@enloe.org

MARY FOLEY, RN, PhD
Director, Center for Nursing and Innovation
UCSF, School of Nursing
2 Koret Way, N631, Box 0610
San Francisco, CA 94143
(415) 514-3638
mary.foley@nursing.ucsf.edu

AMY GUTIERREZ, Pharm.D
Director, Pharmacy Affairs
Los Angeles County Department of Health Services
313 N. Figueroa, Ste. 701
Los Angeles, CA 90012
(213) 240-7717
agutierrez@dhs.lacounty.gov

JILLIAN HACKER
Government Affairs Manager
California Society of Health-System Pharmacists
1314 H Street, Suite 200
Sacramento, CA 95814
(916) 447-1033
jillian@cshp.org

VIRGINIA HEROLD
Executive Officer
California Board of Pharmacy
1625 N. Market Boulevard, Suite N-219
Sacramento, CA 95834
(916) 574-7911
Virginia_Herold@dca.ca.gov

RORY JAFFE, MD
Executive Director
California Hospital Patient Safety Organization
1215 K Street, Suite 930
Sacramento, CA 95814
(916) 552-7568
rjaffe@chpso.org

RANDY KAJIOKA, Pharm.D
Chief of Pharmacy Services
California Correctional Health Care Services
P.O. Box 588500
Elk Grove, CA 95758
(916) 379-1677
randy.kajioka@cdcr.ca.gov

NASIM KARMALI, RPh
Director, Accreditation, Regulation, Licensing
Kaiser Foundation Hospital Redwood City
1150 Veterans Blvd.
Redwood City, CA 94063
(510) 659-8017
nasim.karmali@gmail.com

CARI LEE, Pharm.D
Pharmaceutical Consultant
California Department of Public Health
150 North Hill Drive, Suite 22
Brisbane, CA 94005
(415) 330-6779
cari.lee@cdph.ca.gov

CHRISTINE LOW, Pharm.D.
Manager Medication Safety & Pharmacy Compliance
Scripps System
10666 N Torrey Pines Rd – 303C
La Jolla, CA 92037
(858) 554-4331
Low.Christine@scrippshealth.org

PATRICIA MCFARLAND, RN, MS, FAAN
Chief Executive Officer
Association of California Nurse Leaders
2520 Venture Oaks Way, Suite 120
Sacramento, CA 95833
(916) 779-6949
patricia@acnl.org

ROBERT MENÉT, Pharm.D
Pharmaceutical Consultant II Specialist
California Department of Public Health
P.O. Box 997377; MS 3401
Sacramento, CA 95899-7377
(916) 552-8760
robert.menet@cdph.ca.gov

JOCELYN MONTGOMERY, RN
Director of Clinical Affairs
California Association of Health Facilities
2201 K Street
Sacramento, CA 95816
(916) 432-5197
jmontgomery@cahf.org

LORI NOLAN-MULLENHOUR, MSN, RN, NE-BC, CEN
Providence Little Company of Mary Medical Center Torrance
Director, Women & Children's Service Line
4101 Torrance Boulevard
Torrance, CA 90503
(310) 303-6312
Lorene.Mullenhour@providence.org

DOUG C. O'BRIEN, PHARM. D.
Kaiser Foundation Hospitals
Regional Director for Inpatient Pharmacy Services
Northern California
3240 Arden Way
Sacramento, CA 95825
(510) 301-3990
Doug.C.O'brien@nsmtp.kp.org

LYNN PAULSEN, Pharm. D.
Director, Pharmacy Practice Standards
University of California
Office of the President
1111 Franklin Street
Oakland, CA 94607
(415) 412-6216
Lynn.Paulsen@ucsfmedctr.org

RICHARD B. RABENS, MD, MPH, FAAP
Medical Director
The Permanente Medical Group, Inc/Kaiser Permanente
1800 Harrison Street, Ste. 410
Oakland, CA 94612
(510) 625-6881
richard.rabens@kp.org

SUSAN REED
Director of Pharmacy Operations
Adventist Health
1075 Creekside Ridge Drive
Roseville, CA 95678
(916) 865-1728
susan.reed@ah.org
sareedrx@gmail.com

DAN ROSS, Pharm.D
Representative
California Society of Health-System Pharmacists
1314 H Street, Suite 200
Sacramento, CA 95814
(818) 500-8262
dross@drossconsulting.com

SARAH STEPHENS, PHARMD, BCPS
Medication Safety Coordinator
Kaweah Delta Health Care District
400 W. Mineral King
Visalia, CA 93291
Phone: (559) 308-0783
sastephe@kdhcd.org

ART WOO, Pharm.D
Pharmaceutical Consultant
California Department of Public Health
Center for Health Care Quality
Licensing and Certification Program
850 Marina Bay Parkway, Bldg P
Richmond, CA 94804-6403
(510) 620-3916
Art.woo@cdph.ca.gov

REGIONAL ASSOCIATION REPRESENTATIVES

JENNA FISCHER
Vice President, Quality Improvement / Patient Safety
Hospital Council of Northern and Central California
877 Ygnacio Valley Road, Ste. 210
Walnut Creek, CA 94596
(925) 746-5106
jfischer@hospitalcouncil.net

ALICIA MUÑOZ
Vice President, Quality and Patient Safety
Hospital Assoc. of San Diego & Imperial Counties
5575 Ruffin Road, Ste. 225
San Diego, CA 92123
(858) 614-1541
amunoz@hasdic.org

JULIA SLININGER
Vice President, Quality and Patient Safety
Hospital Association of Southern California
515 South Figueroa, Ste. 1300
Los Angeles, CA 90071
(213) 538-0766
jslininger@hasc.org

Updated 3/25/15

CHA STAFF

BJ BARTLESON, RN, MS, NEA-BC
Vice President, Nursing & Clinical Services
California Hospital Association
1215 K Street, Ste. 800
Sacramento, CA 95814
(916) 552-7537
bjbartleson@calhospital.org

DAVID PERROTT, MD, DDS
Senior Vice President & Chief Medical Officer
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 552-7574
dperrott@calhospital.org

MARLA BARTLE
Administrative Assistant
California Hospital Association
1215 K Street, Ste. 800
Sacramento, CA 95814
(916) 552-7616
mbartle@calhospital.org

Medication Safety Committee Representation

Rev. January 2015

Denotes number of hospitals/health systems represented within that county.

MEDICATION SAFETY COMMITTEE MEMBER GEOGRAPHICS April, 2015

First	Last	Organization	City	Area	County	ZIP
BJ	Bartleson	California Hospital Association	Sacramento	Central	Sacramento	95814
Candace	Fong	Dignity Health	Rancho	Central	Sacramento	95670
Dan	Ross	California Society of Health-System	Sacramento	Central	Sacramento	95814
David	Perrott	California Hospital Association	Sacramento	Central	Sacramento	95814
Dawn	Benton	California Society of Health-System	Sacramento	Central	Sacramento	95814
Doug	O'Brien	Kaiser Foundation Hospitals	Sacramento	Central	Sacramento	95825
Jillian	Hacker	California Society of Health-System	Sacramento	Central	Sacramento	95814
Jocelyn	Montgomery	California Association of Health Facilities	Sacramento	Central	Sacramento	95814
Patricia	McFarland	Association of California Nurse Leaders	Sacramento	Central	Sacramento	95634
Randy	Kajioka	Kaiser Permanente	Sacramento	Central	Sacramento	95825
Robert	Menet	California Department of Public Health	Sacramento	Central	Sacramento	95899
Rory	Jaffe	California Hospital Patient Safety	Sacramento	Central	Sacramento	95814
Sarah	Stephens	Kaweah Delta Health Care District	Visalia	Central	Tulare	93291
Virginia	Herold	California Board of Pharmacy	Sacramento	Central	Sacramento	95834
Art	Woo	California Department of Public Health	Richmond	East	Contra Costa	94804
Cari	Lee	California Department of Public Health	Brisbane	East	San Mateo	94005
Carolyn	Brown	Santa Clara Valley Medical Center	San Jose	East	Santa Clara	95128
Jacalynn	Blankenship	CALNOC	San Ramon	East	Contra Costa	94583
Jeannett	Hanni	Sutter health - Peninsula Coastal Region	Mountain	East	Santa Clara	94040
Jenna	Fischer	Hospital Council of Northern and Central	Walnut Creek	East	Contra Costa	94596
Katie	Choy	Kaiser Pemanente	Oakland	East	Alameda	94612
Lynn	Paulsen	University of California	Oakland	East	Alameda	94607
Mary	Foley	Center for Nursing and Innovation UCSF,	San Francisco	East	San	94143
Nasim	Karmali	Washington Hospital Health System	Fremont	East	Alameda	94538
Richard	Rabens	The Permanente Medical Group, Inc/Kaiser	Oakland	East	Alameda	94612
Kevin	Dorsey-Tyler	Enloe Medical Center	Chico	North	Butte	95969
Sue	Reed	Healdsburg District Hospital	Healdsburg	North	Sonoma	95448
Alicia	Munóz	Hospital Association of San Diego and	San Diego	South	San Diego	92123
Amy	Gutierrez	Los Angeles County Department of Health	Los Angeles	South	Los Angeles	90012
Christine	Low	Scripps System	La Jolla	South	San Diego	92037
Eddie	Avedikian	Providence Holy Cross Medical Center	Mission Hills	South	Santa	91346
Edna	DeLeon	Huntington Memorial Hospital	Pasadena	South	Los Angeles	91105
Frank	Maas	Childrens Hospital Orange County	Orange	South	Orange	92868
Julia	Slininger	Hospital Association of Southern California	Los Angeles	South	Los Angeles	90071
Lori	Nolan-	Providence Little Company of Mary Medical	Torrance	South	Los Angeles	90503
Mary	Cone	Sharp Grossmont Hospital	San Diego	South	San Diego	91942
Nancy	Blake	Childrens Hospital Los Angeles	Los Angeles	South	Los Angeles	90027

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 8, 2015

TO: Medication Safety Committee

FROM: Marla Bartle, CHA Staff

SUBJECT: Member Updates

NEW MEMBERS

No new members.

MEMBER RESIGNATIONS

Terri Gately has increased work responsibilities and cannot devote the time to the committee.

Jerry Kim and Dana Radman are no longer at their respective positions at member hospitals.

MEMBER CANDIDATES

No new member candidates.

Medication Safety Committee Attendance

As of January 2015

MEMBER NAME					Total 2012					Total 2013					Total 2014					Total 2015
	12-Jan	18-Apr	25-Jul	10-Oct		9-Jan	10-Apr	10-Jul	9-Oct		8-Jan	9-Apr	9-Jul	8-Oct		7-Jan	8-Apr	8-Jul	7-Oct	
Eddie Avedikian	Y	Y	Y	Y	4	N	N	Y	Y	2	Y	Y	N	Y	3	Y				1
Dawn Benton	Y	Y	Y	Y	4	N	Y	Y	Y	3	Y	Y	Y	N	3	N				0
Nancy Blake	Y	Y	N	N	2	Y	Y	N	Y	3	Y	N	Y	Y	3	N				0
Jacalynn Blankenship	--	--	--	--	--	--	--	--	--	0	--	--	Y	Y	2	Y				1
Carolyn Brown	Y	Y	Y	Y	4	Y	Y	Y	N	3	Y	N	Y	N	2	Y				1
Katie Choy (2013)	--	--	--	--	--	--	N	Y	Y	2	Y	N	N	N	1	N				0
Edna DeLeon	Y	Y	Y	N	3	Y	N	N	N	1	N	N	N	Y	1	N				0
Kevin Dorsey-Tyler	--	--	--	--	--	--	--	--	Y	1	N	N	Y	N	1	Y				1
Mary Foley	Y	N	Y	N	2	N	Y	Y	Y	3	N	N	Y	Y	2	Y				1
Candace Fong (2013)	--	--	--	--	--	--	Y	Y	Y	3	Y	Y	Y	Y	4	Y				1
Amy Gutierrez	Y	Y	Y	Y	4	Y	N	Y	Y	3	N	Y	Y	Y	3	Y				1
Jillian Hacker	--	--	--	--	--	--	--	--	--	0	--	Y	Y	Y	3	Y				1
Jeannette Hanni	Y	N	Y	Y	3	Y	Y	Y	Y	4	Y	Y	Y	Y	4	Y				1
Virginia Herold	Y	Y	Y	Y	4	Y	Y	Y	N	3	N	Y	Y	N	2	Y				1
Rory Jaffe	Y	Y	Y	Y	4	Y	Y	Y	Y	4	Y	Y	Y	Y	4	N				0
Randy Kajioka	Y	Y	N	N	2	N	N	N	N	0	N	N	Y	Y	2	N				0
Nasim Karmali	Y	Y	Y	N	3	Y	N	N	Y	2	Y	N	Y	Y	3	Y				1
Cari Lee (2012)	--	Y	Y	Y	3	Y	Y	Y	N	3	Y	Y	N	N	2	Y				1
Christine Low (2015)															0	Y				1
Patricia McFarland	Y	N	N	N	1	N	Y	Y	Y	3	N	N	N	N	0	N				0
Robert Menet	Y	Y	Y	Y	4	Y	N	N	N	1	Y	N	Y	N	2	Y				1
Jocelyn Montgomery	--	--	--	--	--	--	--	--	--	0	--	--	Y	Y	2	Y				1
Lori Nolan-Mullenhour (2014)	--	--	--	--	--	--	--	--	--	0	--	--	N	Y	1	Y				1
Doug O'Brien (2014)	--	--	--	--	0	--	--	--	--	0	--	--	N	Y	1	Y				1
Lynn Mulchay Paulsen (2014)	--	--	--	--	0	--	--	--	--	0	--	--	N	Y	1	Y				1
Richard Rabens	N	Y	N	N	1	N	N	Y	N	1	N	N	Y	Y	2	Y				1
Sue Reed (2013)	--	--	--	--	--	--	Y	N	N	1	Y	Y	Y	N	3	N				0
Dan Ross (2012)	--	--	Y	Y	2	Y	Y	Y	N	3	N	Y	Y	Y	3	Y				1
Sarah Stephens (2015)	--	--	--	--	0	--	--	--	--	0	--	--	--	--	0	Y				1
Art Woo (2012)	--	--	--	Y	1	N	N	N	Y	1	Y	N	N	Y	2	N				0
Regional Reps																				
Jenna Fischer (HCNCC)	N	Y	Y	Y	3	Y	N	Y	N	2	Y	N	N	N	1	N				0
Alicia Munoz (HASDIC)	--	--	Y	Y	2	Y	Y	Y	Y	4	Y	N	Y	N	2	Y				1
Julia Slininger (HASC)	N	Y	Y	Y	3	N	Y	N	Y	2	Y	N	N	N	1	N				0
CHA Staff																				
BJ Bartleson	--	--	--	--	0	Y	Y	Y	Y	4	Y	Y	Y	Y	4	Y				1
David Perrott	--	--	--	--	0	Y	Y	N	N	2	N	N	N	N	0	N				0

Medication Safety Committee Attendance

As of January 2015

Deleted

Andrew Lowe	N	N	N	N	*0*	N				*0*					*0*					*0*
Diane Brown	N	**Y**	**Y**	N	*2*	N	**Y**	**Y**	N	*2*					*0*					*0*
Mary Ann Cone	N	N	N	N	*0*	N				*0*					*0*					*0*
Loriann DeMartini	**Y**	**Y**	**Y**	**Y**	*4*	N	N	N	N	*0*					*0*					*0*
Steve Gold	N	N	N	N	*0*	N				*0*					*0*					*0*
Mary Jann	--	N	N	N	*0*	N	N	N	N	*0*					*0*					*0*
Jan Kiely	N	N	**Y**	N	*1*	N	N	N	N	*0*					*0*					*0*
Jocelyn Montgomery	--	N	N	N	*0*	N				*0*					*0*					*0*
Cleo Mutebi (2012)	--	--	--	**Y**	*1*	**Y**	**Y**			*2*		**Y**			*1*					*0*
Elizabeth Oyekan	**Y**	N	N	N	*1*	N				*0*					*0*					*0*
Allen Schaad	**Y**	N	N	N	*1*	N				*0*					*0*					*0*
Jeffrey Uppington	N	N	N	N	*0*	N				*0*					*0*					*0*
Frank Maas	N	N	N	N	*0*	N				*0*					*0*					*0*
Jonathan Nelson (2012)	--	--	**Y**	**Y**	*2*	N	**Y**	**Y**	**Y**	*3*	**Y**		N	N	*1*					*0*
Pamela Richter	**Y**	**Y**	**Y**	N	*3*	**Y**	**Y**	**Y**	N	*3*	N	N	N	N	*0*					*0*
Lynne Whaley Welty	**Y**	**Y**	**Y**	N	*3*	**Y**	N	**Y**	N	*2*	**Y**	N	N	N	*1*					*0*
Jim Hauenstein	**Y**	N	N	**Y**	*2*	**Y**	N	**Y**	N	*2*	N	N	N	N	*0*					*0*
Terri Gately	**Y**	**Y**	N	**Y**	*3*	N	**Y**	N	N	*1*	N	N	N	N	*0*					*0*
Dana Radman	N	N	**Y**	N	*1*	**Y**	N	N	N	*1*	N	N	N	**Y**	*1*	N				*0*
Jerry Kim (2013)	--	--	--	--	--	--	**Y**	N	N	*1*	N	N	N	N	*0*	N				*0*

GUIDELINES FOR THE CALIFORNIA HOSPITAL ASSOCIATION MEDICATION SAFETY COMMITTEE

I. NAME

The name of this committee shall be the Medication Safety Committee.

II. MISSION

The mission of the Medication Safety Committee is to provide leadership within the health care community to promote the highest standards related to the safe and effective use of medications.

III. PURPOSE

The purpose of the Medication Safety Committee is to provide a forum for diverse multi-disciplinary health care organizations, which includes health care delivery organizations, patient safety organizations, discipline specific professional associations/organizations and regulatory agencies, to promote safe medication practices in the state of California. The Committee will focus on acting as a source of medication safety expertise, providing a venue for the coordination of medication safety activities and making recommendations related to medication safety legislation and regulations.

IV. COMMITTEE

The Committee (the "Committee") shall consist of a minimum of 16 representatives and not more than 35 representatives from the following organizations:

California Department of Public Health
California Society of Health System Pharmacists
California Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Association of California Nurse Leaders
California Medical Association
California Hospitals Patient Safety Organization
Risk Management Association
Representatives from the following CHA committees/centers:
- Center for Behavioral Health
- Rural Health Center
- Quality Committee
- Joint Committee on Accreditation and Licensing
- Center for Hospital Medical Executives
- EMS/Trauma Committee
- Hospital Based Clinics Committee
- Center for Rehabilitation Services

Hospital Services for Continuing Care Committee
Governance
Quality Directors
Health Informatics and Technology Committee

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the committee. Non hospital member representatives can only be appointed to the Committee at the discretion of the CHA President.

2. In addition to the Committee/Centers named above, the CHA Committee members shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities and specialty facilities. A member may fulfill more than one required membership.

3. Hospital members are appointed by CHA Staff.

4. Term:

(a) The initial term of office shall be three years, except that one-half of the initial members shall be appointed to two-year terms to ensure continuity of committee members in the future.

(b) As the terms of the members appointed in 2009 expire, or members otherwise leave, vacancies shall be filled to achieve the requirements of Article IV. Members are limited to two, three-year consecutive terms. An exception shall be granted in cases where a member is elected as a chair officer. Following two consecutive terms there must be a one-year interval before a member is eligible for another term.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee.

2. Identify issues and develop possible solutions and best practices to improve the safety of medication storage and distribution administration.

3. Work cooperatively with key stakeholders to develop creative solutions.

4. Provide communication to member hospitals regarding medication safety issues.

5. Maintain/increase awareness of the legislative and regulatory environment with regard to medication safety issues.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly in person.

2. To maintain continuity substitution of members is not acceptable.

3. Three consecutive unexcused absences by a Committee member will initiate a review by the Chair and CHA staff for determination of the Committee member's continued service on the Committee.

4. Special meetings may be scheduled by the Chair, majority vote or CHA staff.

D. VOTING

1. Voting rights shall be limited to members of the Committee, and each member present shall have one vote. Voting by proxy is not acceptable.

2. All matters requiring a vote of the Committee must be passed by a majority of a quorum of the Committee members present at a duly called meeting or telephone conference call.

E. QUORUM

Except as set forth herein, a quorum shall consist of a majority of members present or not less than eight.

F. MINUTES

Minutes of the Committee shall be recorded at each meeting, disseminated to the membership, and approved as disseminated or as corrected at the next meeting of the Committee.

V. OFFICERS

The officers of the Committee shall be the Committee Chair, Vice Chair, Immediate Past Chair and CHA staff.

The Chair shall be elected by the Committee for a two-year term, except for the initial Chair, who shall be appointed by CHA staff for one year. Should a Chair vacate his/her position prior to the end of the term, CHA staff will appoint a replacement to complete the remainder of the term.

Past-chairs will remain as a member of the Committee.

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee

Chair and members and CHA staff for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

The strategic plan defining the goals, objectives, and work plans shall be developed annually by the Committee with approval by CHA staff. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

Staff leadership at the state level shall be provided by CHA with local staff leadership provided by Hospital Council, the Hospital Association of Southern California, and the Hospital Association of San Diego and Imperial Counties. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff shall be an employee of CHA.

VII. AMENDMENTS

These Guidelines may be amended by a majority vote of the members of the Committee at any regular meeting of the Committee and with approval by CHA.

VIII. LEGAL LIMITATIONS

Any portion of these Guidelines which may be in conflict with any state or federal statutes or regulations shall be declared null and void as of the date of such determination.

Any portion of these Guidelines which are in conflict with the Bylaws and policies of CHA shall be considered null and void as of the date of the determination.

Information provided in meetings is not to be sold or misused.

IX. CONFIDENTIALITY FOR MEMBERS

Many items discussed are confidential in nature, and confidentiality must be maintained. All Committee communications are considered privileged and confidential, except as noted.

X. CONFLICT OF INTEREST

Any member of the Committee who shall address the Committee in other than a volunteer relationship excluding CHA staff and who shall engage with the Committee in a business activity of any nature, as a result of which such party shall profit either directly or indirectly, shall fully disclose any such financial benefit expected to CHA staff for approval prior to contracting with the Committee and shall further refrain, if a member of the Committee, from any vote in which such issue is involved.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES

January 7, 2015 / 10:00 a.m. – 2:00 p.m.

California Hospital Association
Sacramento, CA

Members Present: Eddie Avedikian, Jacalynn Blankenship, Carolyn Brown (via phone), Kevin Dorsey-Tyler (via phone), Candace Fong, Mary Foley, Amy Gutierrez, Jillian Hacker, Jeannette Hanni, Virginia Herold, (via phone), Nasim Karmali (via phone), Cari Lee, Christine Low, Robert Menet, Jocelyn Montgomery, Lori Nolan-Mullenhour (via phone), Doug O'Brien, Lynn Paulsen, Farid Nasr (via phone), Richard Rabens, Dan Ross (via phone), Sarah Stephens

Members Absent: Dawn Benton, Nancy Blake, Katie Choy, Edna DeLeon, Terri Gately, Rory Jaffe, Randy Kajioka, Jerry Kim, Patricia McFarland, Dana Radman, Susan Reed, Art Woo

Regional Advisors: Jenna Fischer (absent), Alicia Muňoz, Julia Sliniger (absent)

CHA Staff: BJ Bartleson, Rhonda Filipp, David Perrott (absent), Marla Bartle

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Candace Fong at 10:04 a.m.

A. Member Updates

Ms. Fong welcomed new member Sarah Stephens. Ms. Fong announced Sandra Perkins was no longer on the committee due to a job change.

Action: Ms. Bartleson will send out committee guidelines to the committee

II. MINUTES OF PREVIOUS MEETING

After discussion, it was agreed that the October 8, 2014 minutes need to be amended before a vote could take place.

Action: Ms. Hanni will review her notes from the prior meeting and make corrections. Minutes will be forwarded to BJ Bartleson for final review and then sent out to the committee for a vote.

III. OLD BUSINESS

A. Sterile Compounding Regulations

Ms. Bartleson discussed Board of Pharmacy (BOP) Sterile Compounding letter dated 10/20/14. Ms. Gutierrez stated BOP is reviewing comments. Ms. Herold explained that at the 1/27/15 BOP meeting, the board may either 1)adopt the comments, 2)ask

for elaboration on the existing comments, or 3) dismiss the comments and the process begins again. The BOP has one year to deliberate and release final regulations.

B. Sterile Compounding Matrixes

Ms. Bartleson informed the committee that the matrixes included in the agenda packet are from December, 2014 and are the latest version. There was discussion regarding the matrixes. Ms. Paulsen explained that CSHP had developed a subcommittee to review and update the matrixes. Ms. Paulsen asked that we wait for the CSHP committee to finish their current work before distributing.

C. PharMEDium

A discussion of the 12/24/14 letter from PhaMEDium to Ms. Herold and the BOP occurred among the committee members.

The PharMEDium letter explains their concerns with proposed sterile compounding regulations and the potential dilemma California hospitals will face if they are not allowed to supply them.

The Committee discussed potential solutions, such as legislation to develop specific expectations for outsourcing facilities such as PharMEDium.

Action: Mr. Ross commented regarding Critical Access Hospitals, where no pharmacists are on staff and nurses are handling the medication. Documentation on an alternative process instead of individual batch testing is needed.

IV. NEW BUSINESS

A. CDPH AFL 14-34

Mr. Menet discussed AFL 14-34 regarding the enactment of SB 1039, which does not nullify specific items in Title 22. Therefore, hospitals need to apply for program flex for specific sections.

Action: Ms. Hacker and Mr. O'Brien will work together (with assistance from Mr. Menet) to create a template on how to create a successful program flex for hospitals to use. Time frame: 2 weeks from meeting date.

V. LUNCH BREAK

VI. NEW BUSINESS, CONTINUED

B. SAFE PAIN MEDICINE PRESCRIBING PRACTICES

Ms. Munoz discussed the handout regarding Safe Pain Medicine Prescribing in ED's. Due to the guidelines (which are being used in San Diego and Imperial Counties), ED patients are sometimes dissatisfied and ED's may be getting lower HCAPS scores.

Action: Ms. Bartleson will submit the Safe Prescribing Guidelines and Ms. Munoz's SBAR to CHA CHME and EMS/T Committee for review.

C. GENERIC DRUG PRICING

Ms. Bartleson discussed the article "Generic Prices Take Flight" regarding increasing generic drug prices and asked the committee what they were experiencing regarding this. The Committee responded this is a complex problem with no easy solution, similar to drug shortages. The pharmacists reviewed their present practices to use group purchase organizational forecast tools to be proactive for generic price increases.

Ms. Hanni discussed two web sites she uses for her budget forecasting: Novation Budget Forecasting and National Trends in Prescription Drug Expenses.

Action: Ms. Hanni will forward information about these two sites to Ms. Bartleson.

D. CALIFORNIA MEDICAL BOARD (CMB) CONTROLLED SUBSTANCES GUIDELINES

Ms. Hanni handed out the latest version of the CMB's Controlled Substances Guidelines as an FYI to the committee. Ms. Bartleson asked the committee "How does this affect pharmacists? Mr. O'Brien informed the committee that Kaiser already has existing "corresponding responsibility" guidelines in place to escalated issue if a problem occurs. It was also noted that prescribers and dispensers have until 2016 to sign up for CURES, the state's database known as the Controlled Substance Utilization Review and Evaluation System.

Action: None

E. IMPROVING MEDICATION ADMINISTRATION SAFETY

Ms. Foley handed out an article on practice that guides improvements that she co-wrote andt was recently published in the Journal for Healthcare Quality. In the 1970's Ken Barker wrote an article that stated there was an error rate of 20% in medication administration (MA). This article shows that in 2014, after an extensive trial was completed by CALNOC, MA was at .32%.

Action: None

VII. STANDING REPORTS

A. Board of Pharmacy – Virginia Herold

1. DEA releasing requirements on drug take-back programs
2. Implementing SB 493 and receiving the advanced pharmacist classification
3. All the BOP positions are filled

4. Ms. Herold reminded the group that health system pharmacies could ask for their facility licensing to be done at the same time

B. CDPH – Cari Lee

- They are making progress and moving to Phase II, where one-half of the district offices were _____ and others phased in.

VIII. WORKGROUP REPORTS

- Ms. Hacker reported on the revised sterile compounding matrix tools that were provided to CHA in December. Re-checks are needed by committee members. Once the tools are reviewed by CSHP's committee, they will be sent to CHA.

  Action: CSHP's subcommittee will update and finalize tools.

IX. LEGISLATIVE UPDATES

No legislative updates

X. OTHER BUSINESS

2015 Goals and objectives – Tabled until the next meeting

XI. NEXT MEETING

April 8, 2015 CHA Board Room, Sacramento.

XII. ADJOURNMENT

Having no further business, the committee adjourned at 2:03p.m.

Lab Testing Requirements for Medium and Low Risk Sterile Compounding in 9/5/2014 Proposed Board of Pharmacy Compounding Regulations Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

<table>
<tr><th>Facility Testing</th><th>USP <797></th><th>Board of Pharmacy (BOP) Proposed</th></tr>
<tr><td>Viable surface sampling</td><td rowspan="2">Every six months: requires identification of every Colony Forming Units (CFUs) to the genus level and action plan for CFUs exceeding USP thresholds
<table>
<tr><th>Location</th><th>Viable airborne</th><th>Viable surface</th></tr>
<tr><td>ISO-5 (PEC)</td><td>>1</td><td>>3</td></tr>
<tr><td>ISO-7 (Buffer)</td><td>>10</td><td>>5</td></tr>
<tr><td>ISO-8 (Anteroom)</td><td>>100</td><td>>100</td></tr>
</table></td><td>• Monthly for low and medium risk California Code of Regulations (CCR) §1751.4 (i)
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</td></tr>
<tr><td>Volumetric Air sampling by impaction: viable</td><td>• Every six months for low and medium risk
• Weekly for high risk
• Genus level identification of CFUs exceeding the threshold (facility determined)</td></tr>
<tr><td>Volumetric air sampling by impaction: non-viable particle counts</td><td>Every six months: requires action plan for particle counts exceeding ISO class as required</td><td>• Every six months as part of hood re-certification for low and medium risk
• Weekly for high risk</td></tr>
<tr><td colspan="3">Process Validation: The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation</td></tr>
</table>

Personnel	When required	What Tests Are Required	Where Is The Requirement (BOP and USP)
Moderate risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing CCR §1735.1(n)	CCR §1751.6 (e) (1) (E) and §1751.7 (b)
Moderate risk compounding – ongoing competency	Annually as part of the competency testing process		
High risk compounding – initial competency	Prior to the first compound prepared for a patient		
High risk compounding – ongoing competency	Every 6 months as part of the competency testing process		
Product Batching (More than one of the identical product)			
Following manufacturer written communication (package insert or letter)	No requirement; facility policy should describe processes as determined by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) to assure sterility and accuracy of sterile compounding processes within the facility		CCR §1751.7(b)

End Product Testing: The Requirement For Sterility And Potency Testing Per Batch	Comments	USP<797>	BOP proposed July 30,2014
Beyond Used Dating (BUD) is the lesser of the USP<797> or the manufacturer package insert/written communication	• Meets all PEC ISO 5 Requirements • Low risk: 48 hour RT, 14 days refrigeration • Medium risk: 30 hour RT, 9 days refrigeration	• As long as the shorter of the manufacturer insert stability and the USP<797> BUD is met, there is no batch sterility testing requirement	• "appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(I)
Extended BUD (USP<797>)	• The USP<797> BUDs are an exemption from the USP<71> sterility testing • BUD can only be extended if sterility tests according USP<71> are performed • USP<797> does not exempt extended BUDs from sterility testing	• No exemption for sterility testing for extended BUD • Every batch of extended BUD requires sterility testing and sequestering	• "appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(I)
Potency testing is the USP monograph described testing of potency	Products should have one of the following: • A manufacturer sanctioned process • A published (refereed journal) method followed exactly • Lab data from testing of facility product	• No requirements in USP<797>	• Will require potency testing • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(I)
Low/Med Risk Batch: "Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient. "Batch" does not refer to the process of preparing multiple, disparate sterile compounds for an upcoming time period – frequent cause of misunderstanding, as in the "morning batch."			

Temperature Monitoring Requirements in 9/5/2014 Proposed Board of Pharmacy Sterile Compounding Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

TEMPERATURE REQUIREMENTS								
Temperature Description	**Degrees Centigrade**		**Degrees Fahrenheit**		**Comments/Explanations** (Requires NIST certified temperature monitoring devices (USP <1118>))	**USP 37 NF 32 (2014)** (Used as a reference by the FDA for all Package Inserts)	**CDC Vaccine Storage** (May 2014)	**Board of Pharmacy (BOP) 9/5/2014 Proposed** (references 1995 USP)
	Min	Max	Min	Max				
Freezer (USP)	-25º	-10º	-13º	14º	• Check individual monographs for specific requirements outside this range	General Notices 10.20.10		CA Code of Regulations (CCR) §1731.1 (h)
Freezer (CDC)	-50º	-15º	-58º	5º	• Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Cold	NA	8º	NA	46º		General Notices 10.30.20		
Refrigerated	2º	8º	36º	46º			See CDC Vaccine Storage and Handling Toolkit	BOP defines CCT as 2.2º C to 7.7º C vs. USP and CDC range of 2º C to 8º C CCR §1731.1 (g)
Controlled Cold Temperature	2º	8º	36º	46º	• Transient excursions (0º to 15º C) but the calculated MKT must be ≤ 8º C (46º F) • Transient spikes to 25º C (77º F) (not to exceed 24 hours) if supported by manufacturer's stability in writing	General Notices 10.30.40		
Cool	8º	15º	46º	59º		General Notices 10.30.30		
Room Temperature	Prevailing room temperature					General Notices 10.30.50		CCR §1731.1 (i)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15º to 30º C (59º to 86º F) as long as the MKT is ≤ 25º C (77º F) • Spikes to 40º C (104º F) are permitted for less than 24 hours as long as the MKT is ≤ 25º C (77º F) • Check for specific drugs with narrow ranges	General Notices 10.30.60		
Cleanroom Temperature		≤ 20º		≤ 68º	• In order to compensate for the additional layers of protective garb, this is the general recommendation.			Only appears in BOP 9/5/2014 proposed CCR §1751.4 (j)
Warm	30º	40º	86º	104º		General Notices 10.30.70		
Excessive Heat		>40º		>104º		General Notices 10.30.80		

Mean Kinetic Temperature (MKT) approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation; lower temperatures result in less degradation. MKT calculations weigh the various temperatures by natural logs. Temperature spikes result in a greater increase in MKT than the average temperature, often by a critical 2-5 degrees. The MKT can be calculated by hand, by the temperature monitoring software vendor or by the manufacturer using software to determine the MKT for every product.
Note: Anytime a patient has received a vaccine or drug that is determined to have been out of range longer than allowed by the package insert. In this case, the manufacturer should be contacted immediately because all manufacturers have significant amounts of unpublished stability data by lot number and the patient may not have to be re-dosed.

MONITORING REQUIREMENTS				
Location	**Comments**	**USP 37 NF 33**	**CDC Vaccines** (May 2014)	**BOP Proposed**
Freezers	• Daily lapse time monitoring or continuous monitoring • See CDC Vaccine Storage and Handling Toolkit (CDC website)	Daily	Twice daily	Daily CCR §1735.5 (c) (10) & §1751.5 (b) (5) (A, B, C)
Refrigerators		Daily	Twice daily	Daily CCR §1735.5 (c) (10) & §1751.5 (b) (5) (A, B, C)
Ambient Room	• Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

*** Check with legal counsel before relying on this document (Last updated 9/12/2014)**

Sterile Compounding Frequency of Documentation in 9/5/2014 Proposed Board of Pharmacy Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists*

Frequency	Low and Medium Risk	High Risk
Daily		
Room Temperature	X	X
Refrigerator (Twice a day for vaccines)	X	X
Freezer (Twice a day for vaccines)	X	X
Air pressure differentials or air velocity between adjoining isolation rooms	X	X
MiniHelix differentials for Containment Aseptic Isolator (CAI) and Compounding Aseptic Containment Isolators (CACIs)	X	X
Clean the following with germicidal cleaners and disinfected with suitable agent (sterile isopropyl alcohol): - Counters - Cleanable surfaces - Floors	X	X
Cleaning within the ISO 5 environment (before each shift and before and after each batch)	X-> no alternative for closed system automation	X-> no alternative for closed system automation
Weekly		
Cleaning the following with germicidal cleaners and disinfected with suitable agents (sterile IPA): - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	N/A	X (USP 797-> every 1 mo.)
Viable surface sampling (Colony Forming Units (CFUs) identified to genus)	N/A	X (USP 797-> every 6 mos.)
Volumetric air sampling (Particle count; CFUs, identified to genus)	N/A	X (USP 797-> every 6 mos.)
Monthly		
Cleaning the following with germicidal cleaners and disinfected with suitable agents (sterile IPA): - Exterior workbench - Walls - Ceiling - Shelves - Tables - Stools	X (USP 797-> every mo.)	N/A
Viable surface sampling (CFUs identified to genus)	X (USP 797-> every 6 mos.)	N/A
Bi-Annual		
Volumetric air sampling (Particle count; CFUs, identified to genus)	X	N/A
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Fingertip testing (initially x3)	N/A	x
Media Fill testing for employees	N/A	X
Annual		
Fingertip testing (initially x3)	x	N/A
Media Fill testing for employees	X	N/A
Competency testing (Observation/Written)	X	X

*** Check with legal counsel before relying on this document (Last updated 10/13/2014)**

Physical Plant Requirements in 9/5/2014 Proposed Board of Pharmacy Compounding Regulations
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists *

<table>
<tr><th colspan="5">Non-Hazardous Drugs (Low and Medium Risk)</th></tr>
<tr><th rowspan="2">Location</th><th rowspan="2">Primary Engineering Control (PEC)</th><th colspan="2">Beyond Use Dates</th><th rowspan="2">Comments</th></tr>
<tr><th>Low Risk</th><th>Medium Risk</th></tr>
<tr><td>ISO Class 7 environment with physical separation (0.02-0.05” w.c. positive pressure differential)
OR
Segregated Compounding Area without physical separation (requires air velocity of ≥40 feet per minute from the cleanroom to the anteroom)
CCR §1751.4 (f) & §1250.4 (1-4)</td><td>Any ISO Class 5 PEC:
• ISO Class 5 Laminar Flow Hood
• Biological Safety Cabinet with unidirectional flow
• ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow</td><td>48 hours at 68-77°F
14 days at 36-46°F
45 days at -13-14°F
CCR §1751.8 (a)</td><td>30 hours at 68-77°F
9 days at 36-46°F
45 days at -13-14°F
CCR §1751.8 (b)</td><td>• Requires ISO 5 PEC
• ISO Class 7 Cleanroom
CA Code of Regulations (CCR) §1735.51 & 1250</td></tr>
<tr><td rowspan="3">Any preparation area that is not ISO classed, >ISO 7, or does not meet pressure or air flow differentials
CCR §1751.4 (f) & §1250.4 (1-4)</td><td>• ISO Class 5 Compounding Aseptic Isolators (CAI) with unidirectional flow</td><td>48 hours at 68-77°F
14 days at 36-46°F
45 days at -13-14°
CCR §1751.8 (h)</td><td>30 hours at 68-77°F
9 days at 36-46°F
45 days at -13-14°F
CCR §1751.8 (h)</td><td>• Requires ISO 5 PEC
• Requires PEC manufacturer documentation
CCR §1250.4 (5.3)</td></tr>
<tr><td>• ISO Class 5 Laminar Flow Hood with unidirectional flow
• Biological Safety Cabinet with unidirectional flow</td><td colspan="2">12 hours
CCR §1751.8 (d)</td><td></td></tr>
<tr><td>• No PEC
• PEC that does not meet ISO Class 5 and/or unidirectional flow
• Lack of gowning</td><td>1 hour from time of mixing
CCR §1751.8 (f)</td><td>N/A</td><td>• Immediate use only for low risk non-hazardous agents
• Does not require gowning</td></tr>
<tr><th colspan="5">Hazardous Drugs</th></tr>
<tr><th rowspan="2">Location</th><th rowspan="2">Primary Engineering Control
(All PEC’s ISO class 5 negative pressure unidirectional flow)</th><th colspan="2">Beyond Use Dates</th><th rowspan="2">Comments</th></tr>
<tr><th>Low Risk</th><th>Medium Risk</th></tr>
<tr><td>Negative Pressure Room
0.01” w.c. negative (12 air exchanges per hour)
CCR §1751.4 (g)</td><td>• ISO Class 5 Biological Safety Cabinet, Class II Type A2
• ISO Class 5 Biological Safety Cabinet, Class II Type B2
• Containment Aseptic Compounding Isolators (CACI)</td><td>48 hours at 68-77°F
14 days at 36-46°F
45 days at -13-14°F</td><td>30 hours at 68-77°F
9 days at 36-46°F
45 days at -13-14°F</td><td>• Requires certification every six months
CCR §1751.4 (g)</td></tr>
<tr><td rowspan="3">Positive Pressure Room
Low use defined as not more than 5 preps per week
CCR §1751.8 (e) (2)</td><td>• ISO Class 5 Biological Safety Cabinet, Class II Type A2</td><td colspan="2" rowspan="2">12 hours
CCR §1751.8 (e) (1-3)</td><td rowspan="2">• Requires certification every six months
CCR §1751.4 (g)
• Requires use of Closed System Transfer Devices (CSTDs)
CCR §1751.8 (e) (2)</td></tr>
<tr><td>• ISO Class 5 Biological Safety Cabinet, Class II Type B2</td></tr>
<tr><td>• Containment Aseptic Compounding Isolators (CACI)</td><td>48 hours at 68-77°F
14 days at 36-46°F
45 days at -13-14°F</td><td>30 hours at 68-77°F
9 days at 36-46°F
45 days at -13-14°F</td><td>• Requires certification every six months
CCR §1751.4 (g)
• Requires manufacturer documentation
CCR §1751.4 (h)
• Requires use of CSTDs
CCR §1751.8 (e) (2)</td></tr>
<tr><th colspan="5">Non-Hazardous Drugs Prepared in a Hazardous Drug Primary Engineering Control (Chemo Hood)</th></tr>
<tr><td colspan="5">All drugs prepared in a Hazardous Drug Primary Engineering Control (PEC) must be labeled with HD Cautions</td></tr>
<tr><th colspan="5">Transfer Devices</th></tr>
<tr><td colspan="5">The use of transfer devices (minibag plus, AddVantage, etc.) are not considered compounding and therefore a PEC is not required; however, the use of proper aseptic technique is required.</td></tr>
</table>

State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN, JR.
Governor

December 16, 2014 AFL 14-34

TO: General Acute Care Hospitals (GACHs)
Acute Psychiatric Hospitals (APHs)

SUBJECT: Pharmaceutical Service Changes Made by Senate Bill (SB) 1039

AUTHORITY: Health and Safety Code (HSC) Sections 1250.06, 11150, 11210;
Business & Professions Code (BPC) Sections 4115, 4119.6, 4119.7

This All Facilities Letter (AFL) provides notice of the enactment of SB 1039 (Chapter 319, Statutes of 2014), effective January 1, 2015.

SB 1039 makes the following changes regarding the provision of pharmaceutical services in GACHs:

- *Pharmacy Technicians.* A pharmacy technician, working under the direct supervision and control of a pharmacist in a GACH, may perform any of the following duties:
  - packaging emergency supplies for use in the GACH and the hospital's emergency medical system, or as authorized by BPC section 4119 regarding the furnishing of dangerous drugs/devices for emergency pharmaceutical supply containers;
  - sealing emergency containers for use in the GACH; and
  - performing monthly checks of the drug supplies stored throughout the GACH, with irregularities being reported within 24 hours to the pharmacist in charge and the director or the chief executive officer of the facility in accordance with the facility's policies and procedures (P&Ps).

- *Intern Pharmacists*. Intern pharmacists under the direct supervision and control of a pharmacist may:
  - stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a GACH;
  - inspect the drugs maintained in the GACH at least once per month, with the facility being required to establish specific written P&Ps for such inspections.

- *Furnishing Dangerous Drugs or Dangerous Devices*. A hospital pharmacy servicing a GACH may furnish a dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocols established under the facility's P&Ps as approved according to the policies of the facility's governing board, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or device will be provided.

- *Storage and Maintenance of Drugs*. A GACH shall store and maintain drugs in accordance with national standards regarding the storage areas and refrigerator and freezer temperatures, and otherwise pursuant to the manufacturer's guidelines. Nationally recognized standards would include:

    - *U.S. Pharmacopeial Convention* (USP 34), General Notices and Requirements (link: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/USP34-NF29General%20Notices.pdf), Section 10: Preservation, Packaging, Storage and Labeling.

    - Centers for Disease Control and Prevention: *Vaccines and Immunizations* (link: http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html), the best practice guidance for the storage and handling of vaccines.

The facility's P&Ps must specify the above storage parameters.

SB 1039 makes the following change regarding the provision of pharmaceutical services in both GACHs and APHs:

- Facilities must adopt P&Ps regarding the responsibility for ensuring proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital. Contrary to Sections 70263(s) and 71233(s) of Title 22 of the California Code of Regulations (CCR), GACHs and APHs will no longer be required to consult a pharmacist regarding the repackaging and labeling of these substances, except for areas where sterile compounding is performed.

Several sections of SB 1039 address topics already covered by Title 22. In some instances, the statutory change conflicts with those regulations. Until the department can promulgate revisions to Title 22 that reflect the changes made by SB 1039, facilities seeking to follow the BPC provisions must request and receive program flexibility from their local district office. In order to help facilities identify those conflicts, a comparison table is attached to this AFL. Facilities must submit all program flexibility requests in writing and include supporting documentation such as proposed policies and procedures. The program flexibility request form can be found at the link below.

http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph5000.pdf

Please note that facilities are responsible for following all applicable laws. Any failure of the California Department of Public Health to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the HSC, the BPC, and Title 22 of the CCR to ensure compliance.

If you have questions regarding any of the matters discussed in this AFL, please contact your local district office.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Interim Deputy Director

Attachment

Implementation of SB 1039 and Program Flex Requests

Enactment of SB 1039, on January 1, 2015, directly impacted pharmacy law (Business and Professions Code (B&PC)), and California Health and Safety Code (H&SC). As a result, several regulatory sections of California Code of Regulations (CCR), Title 22, primarily for general acute care hospitals (GACHs), are impacted as potential licensure requirement conflicts may arise. Before a licensed entity may implement those sections of SB 1039 conflicting with Title 22, program flex requests must be submitted and Departmental approval obtained. The following is provided as general guidance.

Implementation of …

Pharmacy Technician: B&PC Section 4115(a) through (h) requires no program flex. Modify policies and procedures as appropriate.

Pharmacy Technician: B&PC Section 4115(i)(1) through (3) affects CCR, Title 22 Section 70263(f)(2) **and** (3), as well as Section 70263(q)(10), and will require a program flex request at **each** affected section. As to performing "checks of drug supplies stored throughout the health care facility," the new law reads "monthly." Section 70263(q)(10), which refers to drug storage area inspections in general, stipulates, "drugs maintained on the nursing unit" are to be "inspected at least **monthly**," and by "a **pharmacist**." However, Section 70263(f)(3), which is specific to nursing unit emergency drug supply inspections, stipulates these be done "**no less frequently than every 30 days**" (also by a **pharmacist**). So, along with your flex request to have a pharmacy technician package and seal emergency supplies and/or inspect drug storage areas, include a separate program flex request to permit inspection of emergency supplies "**monthly.**" This section is GACH specific.

Intern Pharmacist: B&PC Section 4119.6 requires no program flex. This bill does **not** change the scope of practice for an intern pharmacist (IP); i.e., IPs may continue to practice as they always have, under proper pharmacist supervision, in accordance with state law and regulation and facility policies and procedures. Policies and procedures are to address all intern pharmacist activities. This section is GACH specific.

Dangerous drugs, etc.: B&PC Section 4119.7(a) requires no program flex. This section does **not** change any regulatory expectation with regards to "standing orders," "order sets," and "protocols" established under the policies and procedures of the health care facility, etc. This section is GACH specific.

Drug storage: B&PC Section 4119.7(b) requires no program flex. The health care facility's policy and procedure **are** to specify medication storage parameters. While this section is GACH specific, all licensed health care facilities are otherwise expected to address medication storage requirements by regulation as reflected in their policy and procedure.

Intern Pharmacist: B&PC Section 4119.7(c) requires no program flex. This section is GACH specific.

Bulk cleaning agents, etc.: H&SC Section 1250.06 impacts CCR, Title 22, Section 70263(s) in a GACH and requires a program flex. Similarly, Section 71233(s) is so impacted in an acute psychiatric hospital (APH). Modify your policies and procedures and submit them with your program flex.

Write or issue a prescription: H&SC Section 11150 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Prescribing, furnishing or administering controlled substances: H&SC Section 11210 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Guidance for Submitting a "Program Flexibility" Request

Use of form *CDPH 5000 Program Flexibility* is not required, but recommended. Use of facility letterhead is acceptable, as long as the same information as requested on form *CDPH 5000* is provided.

The following assumes use of form *CDPH 5000.*

Under "Subject" simply enter "see below" as space is otherwise limited.

In the box, under "proposed alternate method(s) for meeting the intent of the regulations is," enter the following:

1. The regulation and subparagraph you desire to flex; e.g., "Section 70263(f)(2)." Do not simply enter "Section 70263" as this implies **all** of 70263 *Pharmaceutical Services and General Requirements;* i.e., subparagraphs (a) through (t).
2. Straight forward language for **each** flex request is suggested. For example:

> B&PC Section 4115(i)(1) and (2) conflicts with CCR, Title 22 Section 70263(f)(2). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to restock and seal emergency medication supplies used throughout the facility.
>
> B&PC Section 4115(i)(3) conflicts with CCR, Title 22 Sections 70263(f)(3) and 70263(q)(10). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to: (1) Perform monthly inspections of emergency medication supplies instead of no less frequently than 30 days; and, (2) Perform monthly inspections of the drug supplies in nursing units and areas. Any identified irregularities are to be reported within 24-

hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with facility policy and procedure.

H&SC Section 1250.06 conflicts with CCR, Title 22, Section 70263(s). ***Name of your hospital*** requests program flexibility to adopt policies and procedures whereby a pharmacist is not required to consult on the proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital, except for areas where sterile compounding is performed.

Note: For an acute psychiatric hospital, reference CCR, Title 22, 71233(s) to request a program flex at H&SC Section 1250.06.

3. Repeat the process as outlined in 1 and 2 for **each** regulatory section a program flex is desired.
4. Be sure to include the policy and procedure for **each** program flex request as it serves as your supporting documentation.

Please include a contact person's name and their contact information (email and phone number) should questions arise.

Submit the request form(s) and all pertinent policies and procedures to your assigned CDPH L&C District Office. You can expect a response within 60 days.

Program Flex Tips (in no particular order):

1. Alternate methodology, procedures, etc. are permissible **only** with prior written approval of the Department (CDPH L&C Program);
2. Do **not** implement the requested program flex **before** receiving Departmental approval;
3. The effective date is the date the Department approves the program flex;
4. Approvals granted by the Department **must** be posted immediately adjacent to the hospital's license (see CCR, Title 22, §70123 Posting);
5. It is recommended the pharmacy department maintain a copy of the Department's approval (surveyors will ask for these);
6. Do **not** apply for a time-limited program flex as you will only have to reapply to extend/continue;
7. Ideally, submit the program flex on *CDPH Form 5000* (this is the approved, standardized form*);
8. Be sure to indicate the pertinent Title 22 regulation **and** any applicable subparagraph you desire to flex; e.g., "70263(f)(1)," along with the alternative at the appropriate B&PC and any related subparagraph, e.g., "4115(i)(1)," etc. ("70263" alone, is too broad in scope and unclear);
9. Along with the "program flexibility" request you **must** submit supporting evidence demonstrating how statutory requirements will otherwise be met (e.g., the new/revised policy and procedure);
10. Submitted policies and procedures are reviewed only as reference documents to ascertain the acceptability of the entity's request for a program flex. The review of these documents does not constitute any form of official Departmental approval;
11. Once received, the Department has a 60-day timeframe to approve, approve with conditions or modifications, or to deny the application;
12. Denials and approvals with conditions will be accompanied by justification for any conditions or modifications imposed;
13. SB 1039 adds or modifies statutory language at B&PC (Pharmacy Law) and H&SC (California Law) – it does **not** change regulatory language/licensure requirements at CCR, Title 22, hence, the need for program flex;
14. There is **no** need to request a program flex for intern pharmacist related activities as existing pharmacy law at B&PC §4114 remains unchanged;
15. "Direct supervision and control of a pharmacist" is defined at B&PC §4023.5 (this has not changed);
16. Regardless of who performs an activity (tech or intern pharmacist) their supervising pharmacist remains responsible (this has not changed);
17. Please provide a contact name, direct phone number and email address to facilitate any necessary communication;
18. Please submit your program flex request with all supporting documentation to your District Office;
19. Your "Compliance Officer" may be another resource for you;
20. In a GACH, to implement B&PC §4115(i)(1) through (3) **necessitates** a program flex request for §70263(f)(1) through (3);

21. In a GACH, to implement B&PC §4119.6 would **not** necessitate a program flex (intern pharmacist);
22. H&SC §11150 requires **no** program flex – this section addresses scope of practice;
23. H&SC §11210 requires **no** program flex;
24. In a GACH, to implement B&PC §4119.7(a) requires **no** program flex (reportedly this was added to incorporate the use CPOE/EHR for these types of orders, etc.). The Department would otherwise expect continued compliance with §70263(h)(1) through (4), which addresses "standing orders for drugs";
25. In a GACH, to implement B&PC §4119.7(b) would **not** require a program flex – the entity's policy and procedure does need to specify storage parameters;
26. In a GACH, to implement B&PC §4119.7(c) would **not** require a program flex (intern pharmacist);
27. In a GACH, to implement B&PC §4115(i)(3) **would** require a program flex for §70263(q)(10);
28. In a GACH, to implement H&SC §1250.06 **would** require a program flex at CCR, Title 22, §70263(s);
29. In an acute psychiatric hospital (APH), to implement H&SC § 1250.06 **would** require a program flex at CCR, Title 22, §71233(s);
30. SB 1039 does **not** otherwise impact APHs except at H&SC §1250.06 (see no. 29 above);
31. In **all** instances, facility policies and procedures should accurately reflect what's being done.

*Use of this form Is **not** mandatory, but preferred. Facility letterhead/stationery with all applicable information is also acceptable.

SBAR Safe Pain Medication Prescribing in ED

SITUATION:
Safe Pain Medicine Prescribing in Emergency Departments (ED) has been successfully implemented in San Diego and Imperial Counties. Low satisfaction scores from patients treated in the ED is being partially attributed to the implementation of safe pain medicine prescribing guidelines. It has been recently reported, through anecdote, that low satisfaction scores from ED survey data has been a source of tension and stress between prescribing physicians and experience professionals and administrators.

Financial incentives/penalties associated with the survey results without context and understanding can limit improvement.

BACKGROUND:
In September 2013, Safe Pain Medicine Prescribing in Emergency Departments was launched in San Diego and Imperial Counties by the San Diego and Imperial County Prescription Drug Abuse Medical Task Force.

Specific guidelines have been created to provide pain relief treatment that strives to avoid mistakes or abuse of pain medicine that can cause serious health problems or death.

Reported in the October 2014 update (www.sandiegosafeprescribing.org); "The San Diego Safe Prescribing Project for the ED has received the National Association of Counties Award. California ACEP, the California Medical Association and the California Hospital Association have adopted the guidelines. Los Angeles County has adopted the program for their 77 EDs. Other counties around California are following. "

ASSESSMENT:
ED experience feedback has not been a component of evaluating the effectiveness of the safe pain medication prescribing initiative. There are anecdotes that negative patient experience may result, related to denied opiate prescription. This raises concerns about the tension between patient experience feedback and implementation of safe prescribing practices.

Concern is being expressed by clinicians that there is a perception that patient satisfaction is becoming more important than safety in prescribing, although there has not been a systematic survey to determine the validity or extent of concern.

Patient experience survey is an important measurement tool, and should be used to achieve both high survey scores and safe prescribing practices.

RECOMMENDATION:
Provide guidance to better prepare prescribers to talk with patients about safety of prescription medications.

Provide clear organizational expectations about safe prescribing practices for patients and families to support prescribing ED physicians and staff in following guidelines.

Explore role of patient advisors to help improve the ED experience of patients not receiving a medication prescription in context of safe prescribing practices.

Explore use of empathic communication development to respond to this population.

Develop qualitative inquiry methods to supplement HCAHPS and other survey results. Better/deeper understanding of the results will help prevent inaccurate conclusions and unproductive incentive/penalty schemes.

Develop a modifier when analyzing survey results to quantify the scope of the issue of a dissatisfied response in context of safe prescribing practices.

Educate senior leaders of inherent conflicts within clinical care, that reside in patient expectation/demand and appropriateness/safety of medications (whether opioids, antibiotics, other).

Alicia Munoz, MAS, FACHE, CPHQ
Vice President, Quality and Patient Safety
Hospital Quality Institute

Julie Morath, MS RN
President and CEO
Hospital Quality Institute

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

February 5, 2015

TO: CHA Board of Trustees

FROM: BJ Bartleson, Vice President, Nursing & Clinical Services

SUBJECT: Generic Drug Price Increases

Generic drug pricing has escalated over the past several years because of a myriad of complicated reasons, from manufacturer's dropping service lines, or specific products, drugs shortages and FDA application and processing delays. While historically generic drugs have been the mainstay of pharmaceutical provisions, the generic supply chain is now fragile and limited to a few suppliers. This unequivocally raises costs, leads to shortages and strained purchasing and patient care delivery dilemmas for pharmacists and hospitals.

The subject was raised at CHA's Medication Safety Committee on January 7, 2015. Member pharmacists agreed the issue is occurring across the state. They discussed the ways they work with their group purchasing organizations (GPO's) to proactively prevent as much cost and delivery disruption as possible. They use items such as the GPO and American Society for Health System Pharmacists (ASHP) forecasting tools, for example, the Novation's Annual Drug Budget Forecasting Tool and ASHP National Trends in Prescription Drug Expenditures and Projections, to proactively forecast pharmaceutical costs shifts.

CHA plans to continue discussions with hospitals/health system pharmacists, purchasers, and respective GPO's to better understand the state and federal level GPO advocacy efforts underway to improve generic drug pricing issues.

BJB:lm

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

February 20, 2015

California State Board of Pharmacy
Attn: Lori Martinez
Lori.Martinez@dca.ca.gov
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC AND WRITTEN CORRESPONDENCE

RE: Compounding Regulations, Notice of Proposed Modifications, Articles 4.5 and 7 of Division 17 of Title 16 California Code of Regulations, Section 1735 et seq., 1751 et seq. and 1753. Comment Period: February 6, 2015 to February 20, 2015

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed changes to compounding regulations for hospital pharmacies set forth in Articles 4.5 and 7 of Division 17 of Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.

CHA and its member hospitals agree that, in light of the recent national events with sterile compounding pharmacies, public protection along with efficient, effective delivery of pharmaceutical care is of utmost importance. We agree that updating the state compounding regulations to improve overall patient safety is paramount. We applaud the Board of Pharmacy's willingness to pursue a fair and equitable process in which to make these critical changes, keeping in mind the complexities of the regulations, the enormity of hospital and other pharmaceutical operations, and the pursuit of the highest safety measures for the public we serve.

First and foremost, CHA would like to recognize the California Board of Pharmacy for its flexibility and accommodating approach to afford all stakeholders a voice in the creation and design of sterile compounding regulations that both meet the ultimate goal of patient safety, as well as recognizing the flexibility necessary to address the varied complexities of health care systems, hospitals and organizations across the state. The work done between many stakeholders over the past year has been remarkable, and the exceptional work by the Board of Pharmacy leaders to provide an inclusive, organized, well-orchestrated approach has been commendable. CHA believes the results of these efforts will prove fruitful, not only for these regulations, but with future challenges facing us regarding pharmaceutical regulations.

CHA, CSHP, CHA's Medication Safety Committee and member hospitals, have been actively engaged in detailed conversations over the last year to address the proposed regulations and their continuous modifications over this time period. We have activated a special sub-committee of elite hospital pharmacy leaders to help inform and address issues to enable all hospitals within the state, large and small, to collectively agree on reasonable recommendations for the latest proposal. We have held numerous stakeholder calls with hospital members from rural and urban areas. The varied stakeholders in the CHA Medication Safety Committee enhance problem solving and rapid resolution to complex issues, reflective in this regulatory package. We believe over this year, with all stakeholders involved (the board, hospitals, and CDPH, etc.), that we have educated, negotiated and improved interpretation of the intent of the present recommendations to address both hospital nuances and public safety intentions. The Board of Pharmacy has been an active member of these collaborations to guide, recommend and inform the work.

In review of our participation in this yearlong regulatory process, CHA gave extensive comments in January, 2014 to address the Board of Pharmacy's initial notice of proposed changes in California's compounding regulations. The Board reviewed these extensive comments given by CHA and other stakeholders and made a motion to allow the BOP sterile compounding workgroup to make changes and submit a second version of the proposed text based on the numerous comments. CHA appreciates the consideration of several of its concerns across the body of those proposed regulations. In April, 2014, the board withdrew the current rulemaking file to continue to provide guidance and negotiate new updated language based on all the substantive comments received by the board and notice the revised language as new rulemaking. New proposed regulations were released and CHA submitted comments in July, 2014. At the July, 2014 board meeting, the Board moved to initial notice of proposed changes in the California's compounding regulations located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq. The 45 day comment period ran from September 5, 2014 to October 20, 2014. A regulatory hearing was held on November 4, 2014 to provide the public with an opportunity to provide comments. On January 28, 2015, the board disseminated substantive responses to comments submitted, listened to additional stakeholders' concerns, and elected to open an additional comment period where further stakeholder clarifications could be submitted to the Board. CHA appreciates the Board's patience and recognition of the potential implication of these regulatory changes and welcomes both the manner in which the Board moved through this process and their intense focus on negotiating with all stakeholders in a fair and equitable manner.

We appreciate the Board's recognition and acknowledgement of a majority of changes recommended during the November 4th, 2014 comment period. Over half of our concerns were taken into consideration, from temperature requirement changes, updating language for drug storage and endo- toxin testing, cleaning and disinfecting. Overall, we feel these changes are moving us towards further USP 797 alignment with facility and equipment standards and beyond use dating for sterile compounded drug preparations. We also appreciate the recognition that outsourcing facilities play a key role in hospital pharmacy transactions and that new separate licensing requirements for outsourcing facilities are forthcoming.

Our present recommendations reflect the final points we'd like to offer and expand upon as suggested at the Board of Pharmacy meeting on January 28, 2015. We offer some fine-tuning of language relative to the terms "potency" and "lot", further clarification on equipment standards relative to cleaning, and CFU assessment and management; see Summary of Recommendations below and included in the attached CHA Recommended Comments Grid.

Summary of Recommendations:

1. **1735 Compounding in Licensed Pharmacies**. Add to section (a) a new addition in italics, (5) which states, "*Adding a manufacturer vial to a commercial infusion solution except when part of a proprietary transfer device*" as many hospitals misinterpret the exemptions in the aforementioned 1735.(4) to exclude simple admixture

2. **1735**.1 **Compounding Definitions.** Add to section (t) the following italicized item, so it reads, "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more active ingredients. *It does not mean one or more compounded drug preparations prepared for specific patients in a hospital intended for use within the standard BUD.* The rationale is that when hospitals prepare drugs for patients, this is done in a "batch" with multiple patients receiving the same drug. The "lot" requirements should not apply to these patient specific drugs.

3. **1735.1 (y) Compounding Definitions.** Rewrite section (y) saying, "*"Potency" means active ingredient strength within +/- 10% of the labeled amount except when limited to sterile commercial products when the strength must be calculated as the result of a master formula.* Sterile commercial products are already at +/- 10% so unable to meet this requirement for compounded products.

4. **1751.4 (e) Facility and Equipment Standards for Sterile Compounding.** Add the italicized to section (e) to clarify what gets what type and what frequency of cleaning. *"Counters, tables and cleanable work surfaces shall be cleaned with a germicidal agent, rinsed with sterile water and disinfected with a suitable agent daily. Floors are cleaned with a germicidal agent and rinsed with water daily. Walls ceilings, storage shelving and stools are cleaned with a germicidal agent and rinsed with water monthly.*

5. **1751.4(g) Facility and Equipment Standards for Sterile Compounding.** Change the section references starting on page 28 from, "Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations", to *Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of*

Title 24, Part 4, Chapter 5, of the California Code of Regulations. This more accurately reflects the citation of the 2013 California Building Standards Code. Delete the last sentence in the paragraph that states, "Where the documentation provided by CACI manufacturer does not require garbing only the two glove requirement shall apply. There is confusion regarding the CAI, where garbing is for patient safety and requires less than full garb, and CACI where this is protection for the operator and requires full garb.

6. **1751.4(i) Facility and Equipment Standards for Sterile Compounding (i) –** Replace wording to read, "*The pharmacy must identify the CFU's to the genus level in addition to conduction an investigation. When environmental monitoring action levels are exceeded, the pharmacy shall include an immediate investigation of cleaning and compounding operations and facility management.* Confusion exists regarding the USP 797 language but CFU's must be identified so the facility is aware of the resident bacteria.

CHA, its hospitals, health systems and Medication Safety Committee, appreciates the opportunity to comment on these proposed regulations and looks forward to the ongoing work to provide leadership, collaboration and partnership in pharmaceutical transactions to improve quality and patient safety standards across the state.

Sincerely,

/s/
BJ Bartleson, RN, MS, NEA-BS
Vice President, Nursing and Clinical Services

BJB:mjb
Attachment

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

March 18, 2015

California State Board of Pharmacy
Attn: Lori Martinez
Lori.Martinez@dca.ca.gov
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC CORRESPONDENCE

RE: Compounding Regulations, Notice of Proposed Modifications, Articles 4.5 and 7 of Division 17 of Title 16 California Code of Regulations, Section 1735 et seq., 1751 et seq. and 1753. Second 15-Day Comment Period: March 11, 2015 – March 25, 2015

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed changes to compounding regulations for hospital pharmacies set forth in Articles 4.5 and 7 of Division 17 of Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.

In review of our participation in this yearlong regulatory process, CHA gave extensive comments in January, 2014, to address the Board of Pharmacy's initial notice of proposed changes in California's compounding regulations. The Board reviewed these extensive comments given by CHA and other stakeholders, and made a motion to allow the BOP sterile compounding workgroup to make changes and submit a second version of the proposed text based on the numerous comments. CHA appreciates the consideration of several of its concerns across the body of those proposed regulations. In April, 2014, the board withdrew the current rulemaking file to continue to provide guidance and negotiate new updated language based on all the substantive comments received by the board and notice the revised language as new rulemaking. New proposed regulations were released and CHA submitted comments in July, 2014. At the July, 2014, board meeting, the Board moved to initial notice of proposed changes in the California's compounding regulations located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq. The 45 day comment period ran from September 5, 2014 to October 20, 2014. A regulatory hearing was held on November 4, 2014 to provide the public with an opportunity to provide comments. On January 28, 2015, the board disseminated substantive responses to comments submitted, listened to additional stakeholders' concerns, and elected to open an additional comment period where further stakeholder clarifications could be submitted to the Board. On March 9, 2015, the Board reviewed comments submitted for the First 15-day comment period, February 6th-20th. At that time , due to continued concerns, the

Board elected to open a Second 15-Day Comment Period. CHA is now submitting comments in response to the Second 15-Day Comment Period.

CHA appreciates the Board's patience and recognition of the potential implication of these regulatory changes and welcomes both the manner in which the Board moved through this process and their intense focus on negotiating with all stakeholders in a fair and equitable manner.

CHA's Medication Safety Hospital Pharmacy leaders have discussed at length the progress-to-date on Sterile Compounding regulations. While we are pleased with a majority of changes accepted by the Board, CHA continues to have a concern with the definition of "Potency". Our concerns are threefold. First, the definition presently stated will be mathematically impossible to meet using commercially available products, primarily due to "overfill" by the manufacturers. Second, with the definition as stated in 1735.1(y), a majority of hospitals will not be able to meet the stated requirement. This inability to meet the requirement will result in hospital variances and the ongoing need for program flexibility that will ultimately tax Board and hospital resources, decreasing both Board and hospital efficiency and effectiveness. Third, we are asking for review of the process by which this section of the regulations was reviewed and addressed.

1735.1(y) presently states, "Potency" means active ingredient strength within +/-10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement, Effective December 1, 2014) of the labeled amount. Our concerns are elaborated on below.

First, with the definition as stated, the potency definition will be impossible to meet. For example: A typically compounded product is Vancomycin 1 gram injected into a 250ml bag of normal saline. The 250ml bag is a commercially available product purchased from manufacturers like Baxter or Hospira. Both manufacturers add as much as 25ml of overfill to their bags, which would result in a volume of 275ml. The 1 gram Vancomycin vial from the manufacturer is reconstituted with 20ml of sterile water and added to the 275ml bag of saline, equaling a final volume of 295ml, resulting in a final concentration of 3.39 mg/ml (1000mg/295ml). The labeled potency of the1g/250ml piggyback back would result in a discrepancy of 15% - well above the allowed +/-10%. These are simple compounds from standard manufacturer ingredients and will result in a continuous state of non-compliance with the potency range as defined in the proposed regulations.

Second, with a majority of hospitals unable to meet the definition, hospitals will face the need to submit variances to the Board, which would produce the ongoing need for program flexibility that will ultimately tax Board and hospital resources , decreasing both Board and hospital efficiency and effectiveness.

Third, CHA submitted comments of concern on the potency issue, both in the October 10, 2014, response letter and in the February 12, 2015, response letter. Several CHA pharmacists testified at the January 28, 2015, hearing where it was agree upon between the Board and testifiers that verbal changes would be accepted if given again in writing during the second comment period. That language was given during the second comment period. However, the proposed changes

were rejected as the Board did not have provisional changes in the first round and therefore would not be open for comment in the second round.

Therefore, CHA respectfully asks for reconsideration of section 1735.1(y) in the interest of due process and more efficient operations for both the Board and hospitals. We request this language be changed to read:

1735.1 (y) Compounding Definitions. Rewrite section (y) saying, *“"Potency" means active ingredient strength within +/- 10% of the labeled amount except when limited to sterile commercial products when the strength must be calculated as the result of a master formula.* Sterile commercial products are already at +/- 10% so unable to meet this requirement for compounded products

We appreciate the board’s flexibility and accommodating approach to afford all stakeholders a voice in creation and design of sterile compounding regulations that both meet the ultimate goal of patient safety, as well as recognizing the flexibility necessary to address the varied complexities of health care systems, hospitals and organizations across the state.

/s/
BJ Bartleson, RN, MS, NEA-BS
Vice President, Nursing and Clinical Services

BJB:mjb

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy ("Board") is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on May 6, 2015.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the 45-day written comment period.

The Board, upon its own motion or at the insistence of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Under the authority conferred by Business and Professions Code §4005, in order to implement, interpret and make specific Business and Professions Code §4005, §4231, and §4300, the Board is proposing to amend Articles 2 and 10 of Division 17 of Title 16 of the California Code of Regulations ("CCR"), as follows:

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Board proposes to amend §1715 and §1784 of Articles 2 and 10 of Division 17 of Title 16 of the California Code of Regulations to update and improve the self-assessment forms that pharmacies and wholesalers are required to complete (Form 17M-13, Form 17M-14, and Form 17M-26).

Revise and Update Three Self-Assessment Forms

16 CCR §1715 requires a pharmacist-in-charge (PIC) of a pharmacy licensed under Business & Professions Code ("B&P") §4029 or §4037 to complete a self-assessment before July 1 of every odd-numbered year, and within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the PIC, and he or she becomes the new PIC of a pharmacy. The self-assessment forms are essentially a compilation of relevant laws that apply to community, hospital and compounding pharmacies licensed by the Board. When a PIC goes through the self-assessment form biennially, this helps insure the pharmacy's operations conform to statutory and regulatory requirements, and makes the pharmacy site inspection process more meaningful by providing useful information about controlling statutes and regulations. Self-assessment forms also serve as an easy reference guide for a Pharmacist-in-Charge ("PIC").

16 CCR §1784 requires the Designated Representative-in-Charge ("DRIC") of a wholesaler to complete a self-assessment before July 1 of every odd-numbered year, or within 30 days of (1)

a new wholesaler permit being issues; (2) when there is a change in the DRIC, and (3) when there is a change in the licensed location of a wholesaler to a new address. This self-assessment form assists wholesalers in improving their compliance with legal requirements. The self-assessment also makes the pharmacy inspection process more meaningful and provides relevant information to wholesalers and the DRIC.

Amend 16 CCR §1715

16 CCR §1715 makes reference to two forms, Form 17M-13 "*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment"* (Rev. 01/11) and Form 17M-14 "*Hospital Pharmacy Self-Assessment*" (Rev. 01/11). The proposed amendment of 16 CCR 1715 seeks to update both of the incorporated forms. To accomplish this, along with making changes in the forms themselves, 16 CCR§1715 must be amended so that where the forms are incorporated by reference the date of the latest revision must be updated. Thus, within 16 CCR §1715 the notation (Rev. 10/14) must be substituted for the previous revision date (Rev. 01/11) on both Form 17M-13 and 17M-14.

FORM 17M-13: The Board proposes changes that both remove out-of-date material and add new sections, items, and sub-paragraphs to set out new law and regulations in Form 17M-13 *"Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*." The new law added to this self-assessment is summarized as follows: The Board is adding a specific requirement that pharmacies must be properly lighted, and free from rodents and insects. The Board is removing the word "injectable" from the phrase "sterile injectable drugs" so that the wording is consistent with pending compounding regulations which cover not only injectables, but also cover sterile compounded drugs which are applied in the eye or nose, or inhaled into the lungs.

The Board is shortening the notice period, from within 30 days to within 14 days for when a pharmacy must notify the Board of any licensed individual's admission of theft, diversion or self-use of dangerous drugs, or of chemical, mental or physical impairment affecting their ability to practice. This notice period is similarly shortened for when a pharmacy must notify the Board of receipt of video or documentary evidence of impairment of a licensed individual or of theft, diversion, or self-use of dangerous drugs by a licensed individual. The notice period is also shortened for when a pharmacy terminates a licensed individual for chemical, mental or physical impairment affecting a licensed individual's ability to practice, or the termination of a licensed individual based on theft, diversion or self-use of dangerous drugs. New language is being added to insure the PIC takes responsibility for insuring that all dangerous drugs and devices are not being adulterated, and/or misbranded, and are not expired.

New sections are added to provide guidance in dealing with Voluntary Drug Repository and Distribution ("VDRD") Programs. Pharmacies that donate drugs to VDRD programs must be licensed by and not on probation with the Board, and their primary or sole type of pharmacy practice must be limited to skilled nursing facility, home health care, board and care or mail order. If the pharmacy utilizes a surplus medication collection and distribution intermediary, it must ensure the intermediary is licensed by the Board. No controlled substances shall be donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident

packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under any conditions other than those set by the USP or the product manufacturer. Drugs which were returned from a health facility where the drugs were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Pharmacies that operate a county-approved VDRD program must be licensed by and not on probation with the Board, must be county owned or contract with the county to establish a VDRD program or be owned and operated by a primary care clinic licensed by the California Department of Public Health. Such pharmacies must provide the date they filed a "notice of intent" to participate in a VDRD program with the county health department, must comply with the county's established written procedures, and must provide, on a quarterly basis, to the county health department the name and location of all sources of donated medication it receives.

Pharmacies that receive drugs under a VDRD program must segregate all donated medications from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection, and records of acquisition and disposition of donated medications must be kept separate from the participating entity's other drug acquisition and disposition records. The participating pharmacy must follow the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. No controlled substances may be received. Donated medications received must be unused, unexpired and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under conditions other than those set by the USP or the product manufacture. Drugs which were returned from a health facility where the drugs were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Donated medications must be maintained in the donated packaging until dispensed in a new and properly labeled container, specific to the eligible patient, who has presented a valid prescription. Donated medications received in open containers shall not dispensed under the program or transferred to another participating entity; and once identified, must be quarantined immediately and disposed of in accordance with the Medical Waste Management Act. If a pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county, it must have a written agreement outlining the protocols and procedures for the transfer of donated medications. Donated medication must not transferred by any participating entity more than once. When transferring donated medications, documentation must accompany the medication that identifies the drug name, strength, quantity of medication, the donating facility from where

the medication originated, and a statement that the medication may not be transferred to another participating entity.

New items are being added within existing sections which set out new law addressing additional services pharmacists are now able to supply to patients without a prescription from a physician. Pharmacists now need to be able to look up the controlled substance history of a patient in the CURES Prescription Drug Monitoring Program. Pharmacists are now allowed to perform clinical laboratory tests, both those that require CDPH registration and those that do not. An entire new section is added to set out the duties of an Advance Practice Pharmacist ("APP") which include: pharmacists initiating or adjusting a controlled substance therapy must register with the federal Drug Enforcement Administration. An APP may do patient assessments and interpret drug therapy-related tests, refer patients to other health care providers, and collaborate with other health care providers to evaluate and manage diseases and health conditions. An APP may also initiate, adjust, or discontinue drug therapy, and order tests in coordination with a patient's primary provider or diagnosing prescriber, while transmitting information to a record system shared with the patient's primary care provider or diagnosing provider.

A new item is being added to remind pharmacists that intern pharmacists may not perform any discretionary duties nor act as a pharmacist during a temporary absence of a pharmacist on duty free breaks or meal periods. Pharmacists are to supervise only one technician trainee for only 120 hours or less, and that externship pharmacy technician trainees may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist.

Several new items concern labeling, and now the name of the patient, the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed if indicated on the prescription, must be clustered into one area of the label and comprise at least 50 percent of the label. A label must be highlighted in bold typeface or color and use blank space to set off the mandatory information items, and where applicable, standardized directions must be used. A pharmacy must not dispense more than a 90-day supply of a dangerous drug under these circumstances: -where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills, -where the prescriber has not indicated "no change to quantity" or words of similar meaning, -where the patient has completed an initial 30-day supply (not required where the prescription continues the same medication as previously dispensed in a 90-day supply), -where the total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills, -where the prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary, and -where the pharmacist is exercising his or her professional judgment. When dispensing more than a 90-day supply, the pharmacist must notify the prescriber of the increase in quantity dispensed. A pharmacist must include a label on the drug container which indicates the drug may impair a person's ability to operate a vehicle or a vessel.

Internet prescriptions must only be dispensed on a prescription issued pursuant to a good faith prior examination and internet prescriptions for controlled substances are only dispensed if in

compliance with the Ryan Haight Online Pharmacy Consumer Protection Act. All pharmacists must obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice.

New items are being added to the section regarding Record Keeping Requirements, which include when hypodermic needles and syringes are furnished by a pharmacy, or furnished by a Hypodermic Needle and Exchange Program ("HNEP"), without a prescription, the pharmacy or HNEP must provide the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C, and safe disposal of sharps waste; and provide one or more of the following disposal options: -onsite, safe, hypodermic needle and syringe collection and disposal program, -furnish or make available mail-back sharps containers, -furnish or make available sharps containers.

Several items were added to an existing section about epinephrine. A pharmacy dispensing epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care must follow certain record keeping guidelines. A physician/surgeon must provide a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. The pharmacy must label epinephrine auto-injectors with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only" along with the dosage, use and expiration date. Each dispensed prescription must include the manufacturer's product information sheet for epinephrine auto-injector.

Among other new items, a pharmacy's DEA-controlled substances inventory form must indicate whether the inventory was taken at the "open of business" or at the "close of business." When furnishing controlled substances for physician office use, a pharmacist must ascertain that a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients.

Additional new items concern where a pharmacist must take several steps before dispensing oral or electronically transmitted prescriptions for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or a licensed hospice care. A pharmacist must first reduce the prescription to writing on a pharmacy-generated form, and the licensed facility must provide the pharmacy with a copy of the prescriber's signed order, when available. The prescription must be endorsed by the pharmacist with the pharmacy's name, license, and address, and the physician must have signed the original prescription or provides a facsimile signature on the prescription. The pharmacist must also obtain the signature of the person who receives the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. Any computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. Controlled substance prescriptions written with the "11159.2 exemption" for the terminally ill must be only dispensed when the original prescription is received, and was tendered and partially filled within 60 days with no portion dispensed more than 60 days from the date issued.

Electronic prescriptions (e-scripts) for controlled substances which are received by the prescriber must meet federal requirements.

A new section adds standards of service for providers of blood clotting products for home use ("BCPHU"). Pharmacies that provide such products can be a health system pharmacy, a pharmacy affiliated with hemophilia treatment centers, a specialty home care pharmacy or a retail pharmacy. To do so the pharmacy must have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. A pharmacy must dispense BCPHU to a provider that has sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and must know about proper storage and refrigeration of clotting factors, and maintain a 24-hour on-call service 7 days a week, screening telephone calls for emergencies, acknowledging all telephone calls within one hour or less, and providing access to knowledgeable pharmacy staffing on call 24 hours a day.

To provide BCPHU, the pharmacy must be able to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. The pharmacy supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. The pharmacy must store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. Upon authorization for a nonemergency prescription, a pharmacy must ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less.

Upon approved authorization to dispense a prescription of BCPHU for an emergency situation, provided manufacturer supply exists, a pharmacist delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. A pharmacy provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period A pharmacy that supplies patients with BCPHU must notify patients dispensed these products about Class 1 and Class 2 recalls and withdrawal of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and the pharmacy must participate in the National Patient Notification System for blood clotting recalls. A pharmacist who supplies BCPHU must provide language interpretive services over the telephone or in person, as needed by the patient, and must have a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations.

Pharmacies that furnish emergency contraceptives ("EC") must follow the protocol approved by the Board and the Medical Board, and provide the patient with a copy of the current Board-

approved EC Fact Sheet. Pharmacies furnishing EC must maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol. Prior to furnishing EC, a pharmacist must have completed a minimum of one hour of continuing education ("CE") specific to emergency contraception. Pharmacists who decline to dispense EC or other prescription drug or device pursuant to a conscience clause must notify his or her employer in writing before interacting with members of the public seeking EC. If EC services are not immediately available whether because the mandatory CE has not been completed, or a pharmacist declines to dispense CE pursuant to a conscience clause, the pharmacist must refer the patient to another emergency contraception provider under a protocol that ensures a patient has timely access to the prescribed drug or device.

Pharmacies that furnish naloxone hydrochloride ("Naloxone"), must do so in accordance with the protocol approved by both the Board and the Medical Board of California, which requires providing a fact sheet and a mandatory consultation with the person to whom the drug is furnished. The mandatory consultation must explain opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient. Where possible with the patient's consent, pharmacists must notify the patient's primary care provider of any drug or device furnished to the patient, and if that is not possible, enter the appropriate information in a patient record system.

FORM 17M-14: The Board proposes changes that both remove out-of-date material and add new sections, items, and sub-paragraphs to set out new law and regulations in Form 17M-14 *"Hospital Pharmacy Self-Assessment*:" The new law is summarized as follows: The Board is inserting language to allow an intern, or pharmacy technician, to complete the monthly inspections of all floor stock and drugs maintained in nursing stations.

The Board is shortening the notice period, from within 30 days to within 14 days for when a pharmacy must notify the Board of any licensed individual's admission of theft, diversion or self-use of dangerous drugs, or of chemical, mental or physical impairment affecting their ability to practice. This notice period is similarly shortened for when a pharmacy must notify the Board of receipt of video or documentary evidence of impairment of a licensed individual or of theft, diversion, or self-use of dangerous drugs by a licensed individual. The notice period is also shortened for when a pharmacy terminates a licensed individual for chemical, mental or physical impairment affecting a licensed individual's ability to practice, or the termination of a licensed individual based on theft, diversion or self-use of dangerous drugs.

New items discuss that all unit-dose drugs received from a centralized hospital packaging pharmacy are required to be correctly labeled and barcoded, with the barcode being readable at the patient's bedside. All drugs must be maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines.

A new section was added to cover hospital pharmacies that donate drugs to Voluntary Drug Repository and Distribution (”VDRD”) programs. Those hospitals must be licensed by and not on probation with the Board, and their primary or sole type of pharmacy practice must be limited to skilled nursing facility, home health care, board and care or mail order. No controlled substances shall be donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been received directly from a manufacturer or wholesaler, and they must not have been adulterated, misbranded, or stored under any conditions other than those set by the USP or the product manufacturer. Drugs which were centrally stored must have been under the control of a health facility staff member and never in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. Hospital pharmacies must follow the same procedural drug pedigree requirements for donated drugs as done for drugs purchased from a wholesaler or directly from a drug manufacturer.

An entire new section is being added which sets the duties of an Advance Practice Pharmacist (”APP”). Pharmacists initiating or adjusting a controlled substance therapy must register with the federal Drug Enforcement Administration. An APP may do patient assessments and interpret drug therapy-related tests, refer patients to other health care providers, and participate in the evaluation and management of diseases and collaborate with other health care providers. An APP may initiate, adjust, or discontinue drug therapy, while transmitting information to a record system shared with the patient’s primary care provider or diagnosing provider. Pharmacists may order tests in coordination with a patient’s primary care provider or diagnosing provider, and must transmit that information to a record system shared with the patient’s primary care provider or diagnosing provider.

New items were added that allow Intern pharmacists to stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies, and inspect the drugs maintained in the health care facility at least once per month. Intern pharmacists may not perform any discretionary duties nor act as a pharmacist during a temporary absence of a pharmacist on duty free breaks or meal periods.
Pharmacy technicians may, at the discretion of the pharmacist, remain in the pharmacy while the pharmacist is on a duty free break or meal period, but may only perform non-discretionary tasks. Any task performed by a pharmacy technician during the pharmacist’s temporary absence must be reviewed by the pharmacist. Pharmacy technician duties are expanded to include packaging emergency supplies for use in the health care facility and the hospital’s emergency medical system, sealing emergency containers for use in the health care facility, and performing monthly checks of the drug supplies stored throughout the health care facility and reporting any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer.

New items added to existing sections require that the hospital pharmacy only furnish dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and

protocols established under policies and procedures. Records of centrally stored unused medications donated to a drug repository and distribution program must be kept for three years.

A new section is being added on Centralized Hospital Packaging Pharmacy Practices. A hospital pharmacy may package unit dose medication for the pharmacy for inpatients of one or more hospitals under common ownership within a 75-mile radius: The pharmacy must prepare and store limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. All unit dose medications produced by a centralized hospital packaging pharmacy must be barcoded and readable at the inpatient's bedside. The barcode information must contain: the date the medication was prepared, the components used in the drug product the lot number or control number, the expiration date, the National Drug Code Directory number, and the name of the centralized hospital packaging pharmacy. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

Amend 16 CCR §1784

16 CCR §1784 should be amended so that where it incorporates by reference Form 17M-26 *"Wholesalers of Dangerous Drugs and Devices Self-Assessment* (Rev. 01/11)" the reference to the last update of the form is changed to read (Rev. 10/14).

Form 17M-26: The Board proposes changes that both remove out-of-date material and add new sections, items, and subparagraphs set out new laws and regulations in Form 17M-26 "*Wholesalers of Dangerous Drugs and Devices Self-Assessment.'* The new law is summarized below. Language was added requiring that the designated representative-in-charge must be at least 18 years of age to be responsible for the wholesaler's compliance with all applicable laws. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site.

An entire new section was added specifying the requirements to participate in voluntary drug repository and distribution ("VRDR") programs. Wholesalers may donate medications to a county-approved VRDR program, provided no controlled substances are donated. Drugs that are donated must be unused, unexpired, and in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. Drugs must have been stored under conditions that comply with the standards set by USP or the product manufacturer. Drugs must have never been in the possession of a patient or individual member of the public. Donated medications that require refrigeration must have been stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law.

A new item was added to note the change in federal law that requires, for controlled substances, that the biennial inventory record document must indicate that the inventory was taken at the "close of business" or "opening of business."

Specific Benefits Anticipated: This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances. This regulatory proposal benefits workers' safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work. This regulatory proposal does not affect the state's environment because it simply brings up-to-date mandatory forms which PICs and DRICs already must complete biennially.

While the Board website has updated versions of all three Self-Assessment Forms available for licensees to use, those updated versions have not been through the formal rulemaking process. All changes to the self-assessment forms incorporated by reference in the regulations herein are to be made to the 2011 version of each form, versions formally adopted through the rulemaking process. Superseded or deleted law and regulations are being removed, and new sections, items and sub-paragraphs are added to three self-assessment forms. There are also a number of common non-substantive changes on all three forms. Self-assessments do not impose the new laws. PICs and DRICs are already obligated to comply with new laws and regulations, and the self-assessment form is simply a tool provided by the Board to aid them in doing so. All of the proposed changes, taken together, work to reassure PICs and DRICs that the information and references contained in the forms are current as of the new revision date.

Consistency with and Compatibility with Existing State Regulations: During the process of reviewing and revising the regulations, and amending the self-assessment forms incorporated by reference in §1715 and §1784, the Board has conducted a search of any similar regulations on this topic and has determined that those two regulations, along with regulations concerning compounding and the Compounding Self-Assessment Form, are the only regulations which deal with the Board's mandate requiring pharmacies and wholesalers to conduct self-assessments. The compounding regulations are presently being revised through the formal rulemaking process, and thus the Compounding self-assessment form is not the subject of this update. These proposed revisions and amendments to §1715 and §1784, and the forms incorporated by reference therein, are consistent and compatible with existing state regulations.

Forms Incorporated by Reference: 16 CCR §1715 incorporates by reference both Form 17M-13 "*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*" (Rev. 01/11) and Form 17M-14 "*Hospital Pharmacy Self-Assessment*" (Rev. 01/11). 16 CCR §1784 incorporates by reference Form 17M-26 "*Wholesaler Dangerous Drugs & Devices Self-Assessment*" (Rev. 01/11).

Mandate on Local Agencies or School Districts: This regulatory action does not impose a mandate on local agencies or school districts.

FISCAL IMPACT

A. Cost or savings to any state agency: NONE
B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
D. Other nondiscretionary cost or savings imposed to local agencies: NONE
E. Cost or savings in federal funds to the state: NONE

Effect on Housing Costs: NONE

Business Impact: The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact on directly affected businesses, including the ability of California businesses to compete with businesses in other states.

Results of Economic Impact Assessment: While this regulatory proposal affects pharmacies and wholesalers, it will not have a significant statewide adverse economic impact directly affecting business, or businesses' ability to compete.

Impact on Jobs/New Businesses: The Board has determined that the regulatory proposals herein will not have any impact on the creation or elimination of jobs, of the creation of new businesses or the elimination of existing businesses, or the expansion of businesses in the State of California.

Benefits of the Regulations: This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances. This regulatory proposal benefits workers' safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work. This regulatory proposal does not affect the state's environment because it simply brings up-to-date mandatory forms the PICs and DRICs already must complete biennially.

Cost Impacts: The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Business Report: The proposed regulations do not require a new report to be made. The proposed regulations simply improve, by revising and updating, existing forms that PICs and DRICs must already fill out biennially and when certain enumerated conditions occur. Full compliance by pharmacies and wholesalers with laws and regulations will help insure the health and welfare of all CA residents and help to create a safer work environment for pharmacy and wholesaler employees.

Effect on Small Businesses: The Board has determined that the proposed regulations would not affect small businesses. The Board already requires pharmacists and wholesalers to

complete a self-assessment every two years, so the Board finds that correcting and updating the forms used to conduct self-assessments will have no impact on small businesses.

CONSIDERATION OF ALTERNATIVES: The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations to the Board at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION: The Board of Pharmacy has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

TEXT OF PROPOSAL: Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the person designated below as contact person, or by accessing the Board of Pharmacy's Web site at http:// www.pharmacy.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE: All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below. You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site www.pharmacy.ca.gov.

CONTACT PERSON: Materials regarding this proposal can be found at www.pharmacy.ca.gov. Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

Board of Pharmacy
Attn: Karen Halbo
1625 N. Market Blvd., N219
Sacramento, CA 95834
Telephone: 916-574-7948
Fax No.: 916-574-8616
E-Mail: Karen.Halbo@DCA.ca.gov

(Backup contact person)
Board of Pharmacy
Attn: Lori Martinez
1625 N. Market Blvd., N219
Sacramento, CA 95834
Telephone 916-574-7917
Fax No.: 916-574-8616
E-Mail: Lori.Martinez@DCA.ca.gov

BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulations: Revision of Self-Assessment forms.

The sections affected by these regulations are 16 California Code of Regulations ("CCR") §1715 and 16 CCR §1784 and three forms, adopted by reference with in those regulations, Form 17M-13, Form 17M-14, and Form 17M-26.

Specific Purpose of each Amendment:

Existing regulation at 16 CCR §1715 requires a pharmacist-in-charge ("PIC") of a pharmacy licensed under Business & Professions Code ("B&P") §4029 or §4037 to complete a self-assessment form before July 1 of every odd-numbered year, and within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the PIC, and he or she becomes the new PIC of a pharmacy. 16 CCR §1715 incorporates by reference both Form 17M-13: "*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment* (Rev. 01/11)" and Form 17M-14: "*Hospital Pharmacy Self-Assessment* (Rev. 01/11)." Both of these forms were last updated through the rulemaking process in 2011.

Existing regulation at 16 CCR §1784 requires the Designated Representative-in-Charge ("DRIC") of a wholesaler to complete a self-assessment form before July 1 of every odd-numbered year, or within 30 days of (1) a new wholesaler permit being issues; (2) when there is a change in the DRIC, and (3) when there is a change in the licensed location of a wholesaler to a new address. 16 CCR §1784 incorporates by reference Form 17M-26: "*Wholesaler Dangerous Drugs & Devices Self-Assessment* (Rev. 01/11)." This form was last formally updated through the rulemaking process in 2011.

The problem to be addressed by these regulations is that there have been changes in pharmacy laws and regulations since January of 2011. The Board of Pharmacy ("Board") proposes to amend CCR §1715 and §1784 to update, revise, and improve three self-assessments forms: Form 17M-13, Form 17M-14, and Form 17M-26. These self-assessment forms are essentially a compilation of relevant laws that apply to community and hospital pharmacies and wholesalers licensed by the Board

The anticipated benefits from this regulatory action are that the revised self-assessment forms will continue to help bring about compliance with the law and regulations, and will now include laws and regulations adopted since 2011, and exclude laws and regulations superseded or deleted since 2011. When a PIC or a DRIC goes through the self-assessment form biennially, it helps insure that the pharmacy's or wholesaler's operations conform to statutory and regulatory requirements, and makes the pharmacy and wholesaler site inspection process more meaningful by providing useful information to the PIC or DRIC about controlling statutes and regulations. Self-assessment forms also serve as an easy reference guide for a PIC or DRIC.

Specific Changes and Factual Basis/Rationale

This proposal seeks to amend 16 CCR §1715 and 16 CCR §1784. The only change in the text of those regulations will be updating the existing revision date on the referenced self-assessment forms from "(Rev. 01/11)" to read "(Rev. 10/14)." All other proposed changes are within the three self-assessment forms incorporated by reference in 16 CCR §1715 and 16 CCR §1784. Every change proposed to be made on each form is listed below by form and page number. All proposed changes are to the 2011 version of each form, the last formally amended version.

B&P Code §4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. Pursuant to that mandate, the Board provided licensees with updated versions of these forms on the Board website. This formal rulemaking is undertaken to reduce possible confusion between the last formally approved versions of 2011 and the informally revised versions of 2013 on the website, by codifying all revisions needed to bring all three forms up-to-date.

B&P Code §4300 specifies that every license issued by the Board may be suspended or revoked and is subject to disciplinary action. These revisions reassure PICs and DRICs that the Board is providing them with most current information as of the new revision date, and that compliance with the laws as set out in the form will help them avoid disciplinary action.

FORM 17M-13: The Board proposes all of the changes set forth below be made within Form 17M-13 *"Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*:" These proposed changes both remove out-of-date material and add new sections, items, and sub-paragraphs. The changes result in the renumbering of subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed, in parenthesis, by the new item number if the form is amended as proposed in these regulations.

On every page of Form 17M-13, the footer at the bottom left corner which reads "17M-13 (Rev. 01/11)" should be changed to read "17M-13 (Rev. 10/14)."

On p.1, in the letterhead on the upper right, 3rd line down, move the word "Governor" to be in front of the name Edmond G. Brown Jr. and delete it where it is presently located after the name Edmond G. Brown Jr.

On p.1, in the first paragraph, third sentence, after the words "within 30 days whenever" add a colon ":" before the phrase "(1) a new pharmacy permit …."

On p.1, under "Notes:" in the first sentence, after the phrase "… dispenses prescriptions for outpatient use," delete the word "a" and insert the word "this" Continuing in this sentence, after the words "… use, this Hospital Outpatient" insert the word "Pharmacy" before the words "Self-Assessment." In the second sentence, add a period after the words "Hospital Pharmacy Self-

Assessment." Revise the citation (17M-14 Rev. 01/11) to read "(17M-14 Rev. 10/14)" with no additional punctuation after the closed parenthesis.

On p.1, 4th line up from the bottom, after the line that reads "Licensed Sterile Compounding Permit # _____Expiration: _____ , on the next line down, delete the word "or" before the word "Accredited by:" and insert the word "(optional)" placed in parenthesis after the words Accredited by:".

On p.1, 2nd line up from the bottom, after the word "Hours," and before the word "Daily," insert the word "Weekdays." Then delete the word "Daily."

On p.2, for each numbered item on this page, lined up in a column underneath each entry that lists "RPH #" add the word "APP#" with a line after it. Continuing this line, below each entry that reads "Exp. Date," add the words "Exp. Date:" with a line after it. Below that, still lined up in a column, now underneath the entry that lists "RPH#" add the word "DEA#" with a line after it. Continuing along this new line, below each entry that reads "Exp Date," add the words "Exp. Date:" with a line after it. Add those to each of the items numbered 1-11.

On p.2, delete the lines 12-15.

On p.3, under section "**1. Facility**" at item 1.4, delete the period at the end of the sentence after the words "orderly condition" insert a comma and add the words "properly lighted and free from rodents and insects." *This was added at the request of our field inspectors.*

On p.3, at entry 1.10, first line, remove the word "injectable" from the phrase "sterile injectable drugs." On the second line, remove the words "section 24" and insert the phrase, "section 39 through 51," and after the word "Compounding" add the words "Sterile Drugs". *This change harmonizes the form with the new compounding regulations (initially noticed on Sept. 5, 2014), which encompass not only sterile injectable drugs, but also sterile drugs to be placed in the eye, the nose, or inhaled.*

On p.4, in entry 1.13, in the first sentence, change "within 30 days" to read "within 14 days". *This item was based on B&P §4104(c) which was amended to shorten the notice period to 14 days (Amended Stats 2011, Chapter 646).*

On p.5, under the heading "**2. Delivery of Drugs**" at item 2.1, correct the typing error that misspelled the word "premise" add an "s" at the end so that it reads "premises."

On p.5, for all of the numbered sub-paragraphs under Item 2.2, and a period between the second and third numbers so the numbered sub-paragraphs read: "2.2.1, 2.2.2, 2.2.3, 2.2.4, and 2.2.5."

On p.5, under the heading "**3. Drug Stock**" in front of the one item there, insert the number "3.1"

On p.5, under the heading "**3. Drug Stock**" insert a new item 3.2 which reads:

☐☐☐ 3.2 Dangerous drugs or dangerous devices are purchased, traded sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

☐ 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.

☐ 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.

☐ 3.2.3. Are not expired.

This item and sub-paragraphs were based on B&P §4104(c) which now includes these requirements (Amended Stats 2014, Chapter 507).

On p.5, insert a new section 4, which reads:

4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

☐☐☐ 4.1 Does the pharmacy donate to or operate a County-Approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 of this Self-Assessment)

This item is based on H&S §150200 (Amended Stats. 2012, Chapter 709) and refers to H&S §150204 (Amended Stats. 2014, Chapter 155).

On p.5, and going forward, renumber section "**4. Pharmacist-in-charge (PIC)"** to make it section **5**. Also renumber the items under former section 4 to now be items of section 5, deleting the references made to 4, making items 5.1, 5.21, 5.3, 5.4, 5.5, 5.6, and 5.7 (an item 5.8 will be inserted).

On p.5, under "Pharmacist-in-Charge" insert a new section 4.8 (in the revised version, section 5.8) which reads:

Yes No N/A

☐☐☐ 5.8. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration form from DCPH to conduct such tests. [H&SC 1206, 1265).

This item is based on H&S §1206 and §1265 which were amended.

On p.5, renumber heading for section "5**. Duties of a Pharmacist**" from 5 to **6**.

On p.6, add a new item 6.1 which reads:

Yes No N/A

☐☐☐ 6.1 The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmit a valid prescription to another pharmacist; administer drugs and biological products ordered by the prescriber; manufacture, measure, fit to the patient or sell and repair dangerous devices or furnish instructions to the patient or patient representative concerning the use of the dangerous devices; provide consultation, training and education to patients about drug therapy disease management and disease prevention; provide professional information and participate in multidiscipline review of patient progress; furnish medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement product, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administer immunizations pursuant to a protocol; order and interpret tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052).

This item was based on B&P §4052 which was amended to include these requirements (Amended Stats 2013, Chapter 469).

On p.6, in item 5.2, (in the revised version, item 6.2), correct the typing error that misspelled the words "per formed" making it now read "performed." Later in the same section, after the phrase "… facility a licensed clinic" add the phrase "and a licensed home health agency" before the phrase "in which there is physician oversight," Still later in same section, after the phase "…biologicals by injection" add the words "initiating and" before the phrase "adjusting the drug regimen". *This item was based on several sections cited at the end of this item, including B&P §4052(a)(5), which was amended to include these requirements (Amended Stats 2013, Chapter 469).*

On p.6, after item 5.2, add a new item (in the revised version, item 6.4), which reads:

Yes No N/A

☐☐☐ 6.4 Pharmacists are able to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

This item is based on H&S §11165.1.

On p.6, renumber item 5.3 to be item 6.5.

On p.6, in item 5.3 (in the revised version, item 6.5), after the phrase "…contraceptive pursuant to" add the word "the" before the phrase "statewide protocol found …"

On p.7, after item 5.3 (in the revised version item 6.5) add two new items 6.6 and 6.7 which read:

Yes No N/A

☐☐☐ 6.6 Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (H&SC 1206.6[a])

Yes No N/A

☐☐☐ 6.7 Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (H&SC 1206.6)
CDPH (CLIA) Registration #:_____ Expiration: _____

These items are based on H&S §1206.

On p.7, please check the renumbering of the items in former section 5, deleting the references made to 5, and resulting in items 6.1, 6.2, 6.3, 6.4, 6.5, 6.6 and 6.7.

On p.7, after what in the new version is all of item 6, insert a new heading "**7. Duties of an Advance Practice Pharmacist**" with subsequently and sequentially labeled sub-paragraphs and sub-sub-paragraphs 7.1, 7.2, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, and 7.2.6. This entire new section reads:

7. Duties of an Advance Practice Pharmacist

Yes No N/A

☐☐☐ 7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

Yes No N/A

☐☐☐ 7.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

☐ 7.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;

☐ 7.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;

☐ 7.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])

☐ 7.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate

information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])

☐ 7.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])

☐ 7.2.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

These items and sub-paragraphs were based on B&P §4016.5 (Added Stats. 2010, Chapter 653), B&P §4210 (Added Stats. 2013, Chapter 469), and B&P §4052 (Added Stats 2013, Chapter 469), which, taken together, create and define an Advanced Practice Pharmacist.

On p 7, renumber the section heading "**6. Duties of an Intern Pharmacist"** from number 6 to number **8**, and renumber the subsequent sub-paragraphs sequentially, 8.1, 8.2, 8.3, and 8.4.

On p. 7, add a new section 6.4 (in the revised version, item 8.4) which reads:

Yes No N/A

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

This item was based on 16 CCR 1714.1(d)(Operative 1-1-2000), and was added at the request of our field inspectors asking that this part of the regulation be given greater emphasis by adding it within the form.

On p.7, renumber the section heading of "**7. Duties of a Pharmacy Technician**" from number 7 to number **9**, and renumber the subsequent sub-paragraphs sequentially, 9.1, 9.2, 9.3, 9.4, and insert in a 9.5 (see below).

On p.7, add a new item 7.5 (in the revised version, item 9.5) which reads:

Yes No N/A

☐☐☐ A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

This item was based on B&P §4115.5 (Amended Stats. 2005, Chapter 621) and was added due to our field inspectors asking that this section of the law be given greater emphasis by adding it within the form.

On p. 8, renumber the section heading of "**8. Duties of a Non-Licensed Personnel**" from number 8 to number **10**, and renumber the subsequent sub-paragraphs sequentially as 10.1 and 10.2.

On p. 8, under centered heading "**PHARMACY PRACTICE**" renumber the section heading "**9. Consultation/Patient Profile/Review of Drug Therapy**" from number 9 to number **11**, and re-number the subsequent items and sub-paragraphs sequentially, 11.1, 11.1.1, 11.1.2, 11.1.3, 11.1.4, 11.2, 11.3, 11.4, 11.5, and 11.6.

On p.8, in item 9.1 (in the revised version, item 11.1), move the colon presently after the parenthetical citation to sources to before the parenthetical citation to sources. In sub-paragraph 11.1.4, after the phrase "… pharmacist deems it," add the word "is" before the phrase, "warranted in the ..."

On p.9, renumber the section heading "**10. Prescription Requirements**" from number 10 to number **12**, and renumber the subsequent items sequentially, 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, and 12.9.

On p.9, at item 10.8 (in the revised version, item 12.8), after the phrase "written under H&SC 11159.2" add the word and citation "and H&SC 11167.5," before the word "all." After that word "all" add the word "written" before the phrase "controlled substances prescriptions ..." At the end of the item, add the citation H&SC 11167.5" after the citation "H&SC 11164.(a),"

On p. 9 and beyond, renumber the section heading "**11. Prescription Labeling, Furnishing and Dispensing**" from number 11 to number **13**, and renumber the subsequent items sequentially, 13.1, 13.2, 13.3, 13.4, 13.5, 13.6, 13.7, 13.8, 13.9, 13.10 13.11, 13.12, 13.13, and 13.14.

On p. 9, add an item 13.4 with three sub-paragraphs after 11.3 (in the revised version, item 13.3), that reads:

Yes No N/A

☐☐☐ 13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])

☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.

☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.3.1; (CCR 1707.5[a][22])

☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

This item and sub-paragraphs were based on 16 CCR §1707.5 (Added effective 1-1-2011), and are added to harmonize the form with the new amendments to the regulation on patient-centered labeling (effective April 1, 2015).

On p10, in item 11.13 (in the revised version, item 13.14), delete the word “This” which starts the section, and replace it with “The”

On p.10, after item 11.15 (in the revised version, item 13.16) add new items 13.17 with sub-paragraphs and item 13.18 which read:

☐☐☐ 13.17 The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

☐ 13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (B&PC 4064.5[a])

☐ 13.17.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])

☐ 13.17.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13.17.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b])

These items and sub-paragraphs were based on B&P §4064.5 (Added Stats 2012, Chapter 455), and B&P §4074 (Amended Stats. 2013, Chapter 304).

On p. 11, renumber the section heading "**12. Refill Authorization**" from number 12 to number **14**, and renumber the items within the section, 14.1, 14.2, 14.3, 14.4 and 14.5.

On p. 11, renumber the section heading "**13. Quality Assurance and Medication Errors**" from number 13 to number **15**, and renumber the subsequent items and sub-paragraphs sequentially, 15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.6.1, 15.6.2, 15.6.3, 15.6.4, 15.7, and 15.8.

On p. 11, in item 13.3 (in revised version, Item 15.3), within the citation add the letters "CCR" before the numbers "1711(c)(2)(A)."

On p. 12, renumber the section heading "**14. Erroneous or Uncertain Prescriptions/Corresponding Responsibility for Filing Controlled Substance Prescriptions**" from number 14 to number **16**, and renumber the subsequent items sequentially, 16.1, 16.2, 16.3, and 16.4. , 16.5, and 16.6.

On p.12, after item 14.3, add in new items 14.4, 14.5, and14.6 (in revised version items 16.4, 16.5 and 16.6) which read:

Yes No N/A

☐☐☐ 16.4 Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

Yes No N/A

☐☐☐ 16.5. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

Yes No N/A

☐☐☐ 16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])

These items were based on B&P §4067 (Added Stats 2003, Chapter 250), and 21 United States Code §820, 21 United States Code §802 and H&S §11165.

On p. 12, renumber the section heading "**15. Prescription Transfer**" from number 15 to number **17**, and renumber the subsequent items sequentially, 17.1, 17.2, 17.3, and 17.4.

On p. 13, renumber the section heading "**16. Confidentiality of Prescriptions**" from number 16 to number **18**, and renumber the subsequent items sequentially, 18.1, 18.2, 18.3, 18.4, 18.5, and 18.6.

On p. 13, renumber the section heading of "**17. Record Keeping Requirements**" from number 17 to number **19**, and renumber the subsequent items and sub-paragraphs sequentially, 19.1,

19.2, 19.2.1, 19.2.2, 19.2.3, 19.2.4, 19.2.5, 19.2.6, 19.2.7, 19.2.8, 19.3, 19.3.1, 19.3.2, 19.3.3, 19.3.4, 19.3.5, 19.4, 19.4.1, 19.4.2, 19.4.3, 19.5, 19.6, 19.6.1, 19.6.2, and 19.6.3.

On p. 14, after sub-paragraph 13.3.3, insert a new item 17.4 with sub-paragraphs (in revised version, item 19.4 with sub-paragraphs), which reads:

Yes No N/A

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

This item and sub-paragraphs were based on B&P §4145.5 which was amended (Amended Stats 2014, Chapter 331).

On p.14, after item 17.4, insert a new item (in revised version, item 19.6), which reads:

Yes No N/A

☐☐☐ 19.6. The pharmacy dispenses epinephrine auto-injector to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3)

☐ 19.6.1. A physician/surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119[a][1])

☐ 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only”, the dosage, use and expiration date. (B&PC 4119.3[a][1])

☐ 19.6.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2])

This item and sub-paragraphs were based on B&P §4119 (Amended Stats. 2010, Chapter 653) and B&P §4119.3 (Added Stats. 2013, Chapter 725).

On p.14, renumber the section heading "**18. DEA Controlled Substances Inventory**" from number 18 to number **20**.

On p. 14, after item 18.3, add a new item 18.4 (in revised version item 20.4) which reads:

Yes No N/A

☐☐☐ 20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (CFR 1304.11[a])

*This item was based on the Code of Federal Regulations §1304.11 (*79 FR 53562, *amended Sept 6, 2014).*

On p.15, after item 18.16, add item 18.18 (in revised version, item 20.18) which reads:

Yes No N/A

☐☐☐ 20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])"

*This item was based on 21 Code of Federal Regulations §1306.04(b) (*70 FR 36343, amended June 23, 2005), and requested by our field inspectors*.*

On p.14 and beyond, renumber all items on section 18 to read section 10, renumbering the subsequent items sequentially, 20.1, 20.2, 20.3, 20.4, 20.5, 20.6, 20.7, 20.8, 20.9, 20.10, 20.11, 20.12, 20.13, 20.14, 20.15, 20.16, 20.17 and 20.18

On p. 16, renumber the section heading "**19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substances Prescriptions**" from number 19 to number **21**.

On p.16, in item 19.2 (in revised version, item 21.2), after the phrase "An oral" add the phrase "Or electronically transmitted" before the phrase "prescription for a." In the same item, delete the last sentence, but not the citations in parenthesis. At the end of the second to last sentence, delete the period and add "and:" before the parenthetical citations. Below item 19.2 (draft 21.2) add in the following sub-paragraphs which read:

☐ "21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.

☐ 21.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.

☐ 21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

☐ 21.2.4. The signature of the person who received the controlled substance for the

licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)"

These sub-paragraphs were based on the Code of Federal Regulations §1306.11 (75 FR 16307, Mar. 31, 2010) and H&S §11167.5.

On p.16, delete all of item 19.3.

On p.17, within item 19.10 (in revised version, item 21.9), add "CCR" in front of the citation "1717.4(d)."

On p.17, add three new items after item 19.10 (in revised version, items 21.10, 21.11, 21.12) which read:

Yes No N/A

☐☐☐ 21.10. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

Yes No N/A

☐☐☐ 21.11. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

Yes No N/A

☐☐☐ 21.12. Electronic prescriptions (e-scripts) for controlled substances that are received by the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

These items were based on 21 Code of Federal Regulations §1306.08 (75 FR 16307, Mar. 31, 2010), 21 Code of Federal Regulations §1306.05 (75 FR 16307, Mar. 31, 2010), 21 Code of Federal Regulations §1306.11 (75 FR 16307, Mar. 31, 2010), H&S §11159.21, and 16 CCR 1745 (Amended effective 4-1-2014).

On pps.16 and 17, renumber the subsequent items and sub-paragraphs of former Section 19 sequentially, as 21.1, 21.2, 21.2.1, 21.2.2, 21.2.3, 21.2.4, 21.3, 21.4, 21.5, 21.6, 21.7, 21.8, 21.9, 21.10, 21.11, 21.12, and 21.12.

On p. 17, renumber the section heading "**20. Automatic Dispensing/Delivery Devices**" from number 20 to number **22**, and the subsequent items and sub-paragraphs sequentially, 22.1, 22.2, 22.3, 22.3.1, 22.3.2, 22.3.3, 22.4, 22.4.1, and 22.4.2.

On p.18 and beyond, renumber the section heading "**21. Repackaging by the Pharmacy**" from number 21 to number **23**, and renumber the subsequent items sequentially, 23.1, 23.2, and 23.3.

On p.18, item 21.1 (in revised version, item 21.2, within the parenthesis, after the citation, "CCR 17.51" insert a comma and ", 21 CFR Parts 210, 211)"

On p.18 and beyond, renumber the section heading of “Refill Pharmacy” from number 22 to number 24, and renumber the subsequent items and sub-paragraphs sequentially, 24.1, 24.2, 24.3, 24.4, 24.5, 24.6, 24.7, 24.8, and 24.9.

On p.19, insert a new section (in revised version section 25) which reads:

“25. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

☐ 25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

☐ 25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

☐ 25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

☐ 25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

25.2. The pharmacy meets the following requirements:

☐ 25.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])

☐ 25.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])

☐ 25.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])

☐ 25.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])

☐ 25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])

☐ 25.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])

☐ 25.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])

☐ 25.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])

☐ 25.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])

☐ 25.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls.
(HSC 125286.25[j])

☐ 25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ 25.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])"

These items and sub-paragraphs are based on H&S §125286.20 and H&S §125286.25.

On p.19 and beyond, renumber the section heading of "Policies and Procedures" from number 22 to number 26, and renumber the subsequent items and sub-paragraphs sequentially, 26.1,

26.1.1, 26.1.2, 26.1.3, 26.1.4, 26.1.5, 26.1.6, 26.1.7, 26.1.8, 26.1.9, 26.1.10, 26.1.11, 26.1.12, 26.2, and 26.2.1.

On p.19, in item 23.1, sub-paragraph 23.1.2 (in revised version item 26.1, sub-paragraph 25.1.2) delete the word “effects” and insert in it’s stead, the word “affects.” After the phrase, “authorized by his or her license,” insert the phrase “including the reporting to the board within 14 days of receipt or development.”

This item is based on B&P §4104 (a) and (c) (Amended Stats. 2011, Chapter 646).

On p.19, in item 23.1, 23.1.3 after the phrase “drugs belonging to the pharmacy” add the phrase, “including the reporting to the board within 14 days of receipt or development.”

This item is based on B&P §4104 (a) and (c) (Amended Stats. 2011, Chapter 646).

On p.20 add items 23.3 and 23.4 (in revised version, items 26.3 and 26.4) which read:

“Yes No N/A

☐☐☐ 26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][2]? (B&PC 4052, CCR 1746) If yes, does the pharmacy:

☐ 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

☐ 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

☐ 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐ 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist’s refusal to dispense a prescription or order? (B&PC 733[b])

☐ 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)

☐ 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐☐☐ 26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a])

☐ 26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 26.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system."

These items and sub-paragraphs are based on B&P §§733, 4052 (Amended Stats. 2013, Chapter 469), 4052.01 (Added Stats. 2014, Chapter 325), 4052.3 (Amended Stats. 2013, Chapter 469) and 16 CCR §1746 (Amended Effective 7-1-2013).

On p.20, delete the all capitals flush left section heading "COMPOUNDING" Insert a section heading "**27. Compounding**" and renumber item 24 as Item 27. After "Form 17M-39," change the Rev. 01/11 to reach *(Rev. 02/12)," before (CCR 1735.2[j])"

On p.20, renumber the section heading "25. Nuclear Pharmacy" from 25 to 28, and renumber the items 28.1, 28.2, and 28.3.

On p.20, add item 26 (in revised version, item 29) which reads:

"29. Pharmacies that Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

☐ 29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

☐ 29.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

☐☐☐ 29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- ☐ 29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- ☐ 29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC `150202.5[a])
- ☐ 29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])
- ☐ 29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])
- ☐ 29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])"

These items and sub-paragraphs were based on B&P §4169.5 (Added Stats. 2014, Chapter 10) and H&S §§150202.5, 150204, 150204.5.

On p.20, add two new sections after section 25 Nuclear Pharmacy (draft section 29), including sections 29 and 30 which read:

"30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

- ☐ 30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150201[a][1])

- ☐ Is county owned (H&SC 150201[a][1]) or

☐ Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[a][1], 150200)

☐ 30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

☐☐☐ 30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

☐☐☐ 30.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

☐☐☐ 30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

☐☐☐ 30.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

☐☐☐ 30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

☐☐☐ 30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

☐☐☐ 30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

☐ 30.9.1. Are received from authorized sources. (H&SC 150202, 150203)

☐ 30.9.2. No controlled substances are received. (H&SC 150204[c][1])

☐ 30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

☐ 30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

☐ 30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])

☐ 30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

☐ 30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

Yes No N/A

☐☐☐ 30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

Transferring Donated Drugs From One Participating Entity to Another

☐☐☐ 30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

☐☐☐ 30.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

☐☐☐ 30.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

☐☐☐ 30.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

☐☐☐ 30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

☐☐☐ 30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])"

These items and sub-paragraphs were based on H&S §§150200 (Amended Stats. 2012, Chapter 709), 150201 (Amended Stats. 2014, Chapter 10), 150202 (Amended Stats.2014, Chapter 10), 150202.5.(Added Stats.2012, Chapter 709), 150203, 150204 (Amended Stats. 2014, Chapter 155).

FORM 17M-14: The Board proposes all of the changes set out below be made within Form 17M-14 *"Hospital Pharmacy Self-Assessment*:" The proposed changes below both remove out-of-date material and add new sections, items, and subparagraphs. The changes result in re-numbering subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed in parenthesis by the new item number as proposed in these amendments.

On every page of Form 17M-14, the footer at the bottom left corner which reads "17M-14 (Rev. 01/11)" should be changed to read "17M-14 (Rev. 10/14)."

On p.1, under "Notes:" change the revision reference at the end of "Hospital Outpatient Pharmacy Self-Assessment" to read "(17M-13 Rev.10/14)."

On p.1 in the fourth line up from the bottom, below the line that reads "Licensed Sterile compounding Permit #_____ Expiration: _____" delete the word "or" before the phrase "Accredited by:" and immediately after that, insert the word in parenthesis "(optional)" Insert on the next line down, Centralized Hospital Packaging Permit #:_____ Exp. Date: _____"

On p.1, 2nd line up from the bottom, after the word "Hours," and before the word "Daily," insert the word "Weekdays." Then delete the word "Daily."

On p.2, for each numbered item on this page, lined up in a column underneath each entry that lists “RPH #” insert the word “APP#” with a line after it. Continuing across on this line, below each entry that reads “Exp. Date,” insert the words “Exp. Date:” with a line after it. Below that, still lined up in a column, now underneath the entry that lists “APP#” add the word “DEA#” with a line after it. Continuing across on this new line, below each entry that reads “Exp Date:” add the words “Exp. Date:” with a line after it. Add those to each of the items numbered 1-12.

On p.2, in adding the additional lines as referred to above, the lines for listing pharmacy personnel spills over to the next page. Please delete the items 13-18 so the lines for listing pharmacy personnel only fills up one page.

On p.4, in item 2.2, after the phrase “The pharmacist” insert a comma, a space and the words “intern, or pharmacy technician.” *This was added based on B&P §4114(a) (Amended Stats.2005, Chapter 621) and B&P §4115.5 (Amended Stats. 2005, Chapter 621).* At the end of item 2.2, in the citation within parenthesis, before the citation 22 CCR 7026[q][10], insert “B&PC 4119.7[c], 4115[j],”

On p.5, insert in section “**4. Drug Stock**” new items 4.4 and 4.5, which read:

Yes No N/A

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient’s bedside. (B&PC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer’s guidelines. (B&PC 4119.7[b]

This item and sub-paragraphs were based on B&P §§4119 (Amended Stats 2010, Chapter 653), 4128.4 (Added Stats. 2012, Chapter 687) and 4128.5 (Added Stats. 2012, Chapter 687).

On p.5, insert a new section “**5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**” which reads:

5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)

☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])

☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

These items and sub-paragraphs were based on H&S §§150202 (Amended Stats. 2014, Chapter 10), 150202.5 (Added Stats. 2012, Chapter 709), and 150204 (Amended Stats 2014, Chapter 155).

On p.6, renumber the section heading "**5. Pharmacist-in-Charge (PIC)"** from number 5 to number 6, and renumber the subsequent items sequentially, 6.1, 6.2, 6.3, 6.4, and 6.5.

On p.6, renumber the section heading "**6. Duties of a Pharmacist**" from number 6 to number 7, and renumber the subsequent items sequentially, 7.1 and 7.2 .

On p.7, insert a new section "**8. Duties of an Advance Practice Pharmacist"** which reads:

8. Duties of an Advance Practice Pharmacist

Yes No N/A

☐☐☐ 8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

☐☐☐ 8.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

- ☐ 8.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;
- ☐ 8.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;
- ☐ 8.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ 8.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ 8.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[01])
- ☐ 8.2.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

These items and sub-paragraphs were based on B&P §4210 (Added Stats. 2013, Chapter 469), and B&P §4052 (Added Stats 2013, Chapter 469), which created and define an Advanced Practice Pharmacist.

On p.7 and beyond, renumber the section heading "**7. Duties of an Intern Pharmacist**" from number 7 to number 9, and renumber the subsequent items and sub –paragraphs sequentially as in 9.1, 9.1.1, 9.1.2, 9.2, 9.3, and 9.4.

On p.7, under item 7.1 (in revised version, item 9.1) insert sub-paragraphs 9.1.1 and 9.1.2 which read:

- ☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)

- ☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])

These sub-paragraphs were based on B&P §4119.7 (Added Stats. 2014, Chapter 319).

On p.7, insert after item 7.2 (in revised version, item 9.2), a new item 9.3 which reads:

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

This item was based on 16 CCR 1714.1(d) (Operative 1-1-2000), and was added due to our field inspectors asking that this part of the regulation be given greater emphasis by adding it within the form.

On p.7, renumber the section heading "**8. Duties of a Pharmacy Technician**" from number 8 to number **10**, and renumber the subsequent items and sub–paragraphs sequentially as in 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.8.1, 10.8.2, 10.8.3, 10.8.4, 10.8.5, 10.9. 10.9.1, 10.9.2, and 10.9.3. As this spans several pages, please take out any "Yes No N/A" that are not labeling the uppermost boxes on the page, or after a new section, or after lines or a PIC to fill in information, and add in a "Yes No N/A" over the uppermost boxes at the top of each page.

On p.7, after item 8.6, insert a new item 8.7 (in revised version, item 10.7) which reads:

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

This item was based on B&P §4115 (Added Stats. 214, Chapter 319) and 16 CCR 1714.1(d) (Operative 1-1-2000).

On p.8, in sub-paragraph 8.7.4 (the revised version, sub-paragraph 10.8.4), after the words "The pharmacy technician" delete the word "check" and insert the word "checking" in it's stead.

On p.8, in sub-paragraph 8.7.5 (the revised version, sub-paragraph 10.8.5), after the words "of the program that uses" delete the word "specially" and insert the words "specialized and advanced " before "trained pharmacy technicians …"

On p.8, insert a new item 10.9 which reads:

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

This item was based on B&P §4115 (Added Stats. 2014, Chapter 319and B&P §4119 (Amended Stats. 2010, Chapter 653).

On p.8, renumber the section heading "**9. Duties of Non-Licensed Pharmacist**" from number 9 to number **11**, and renumber the subsequent items and sub–paragraphs sequentially as 11.1, and 11.2.

On p.8, under centered heading "**PHARMACY PRACTICE**," renumber the section heading "**10. Pharmaceutical Service Requirements**" from number 10 to number **12**, and renumber the subsequent items and sub–paragraphs sequentially as 12.1, 12.1.1, 12.1.2, 12.1.3, 12.1.4, 12.1.5, 12.1.6, 12.1.7, 12.1.8, 12.1.9, 12.1.10, 12.1.11, 12.1.12, 12.1.13, 12.2, 12.2.1, and 12.2.2. As this spans several pages, please take out any "Yes No N/A" that are not labeling the uppermost boxes on the page, or after a new section, or after lines or a PIC to fill in information, and add in a "Yes No N/A" over the uppermost boxes at the top of each page.

On p.9, renumber the section heading of "**11. Medication/Chart Order**" from number 11 to number **13**, and renumber the subsequent items sequentially as 13.1, 13.2, 13.3, and 13.4.

On p.9, insert new item 13.4 which reads:

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

This item was based on B&P §4119.7 (Added Stats. 2014, Chapter 319).

On p.9, renumber the section heading "**12. Labeling and Distribution**" from number 12 to number **14**, and renumber the subsequent items sequentially as 14.1, 14.2, and 14.3.

On p.10, renumber the section heading "**13. Duration of Drug Therapy**" from number 13 to number **15**.

On p.10, renumber the section heading "**14. Confidentiality of Charge Orders, Prescriptions and Patient Medical Information**" from number 14 to number **16**, and re-number the subsequent items sequentially as 16.1, 16.2, 16.3 and 16.4.

On p.10, renumber the section heading of "**15. Quality Assurance and Medication Forms**" from number 15 to number **17**, and renumber the subsequent items and sub-paragraphs sequentially as 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.6.1, 17.6.2, 17.6.3, 17.6.4, 17.7, and 17.8.

On p.11, renumber the section heading "**16. Record Keeping Requirements"** from number 16 to number **18**, and renumber the subsequent items sequentially as 18.1, 18.2, 18.2.1, 18.2.2, 18.2.3, 18.2.4, 18.2.5, 18.2.6, 18.2.7, 18.2.8, 18.2.9, 18.3, 18.4, 18.5, 18.6, 18.7, 18.8, 18.9, 18.10, 18.11, 18.12, and 18.13.

On p.11, after sub-paragraph 16.2.8 (in revised version sub-paragraph 18.2.8), insert sub-paragraph 18.2.9, which reads:

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1])

This item was based on H&S §150200 (Amended Stats. 2012, Chapter 709), and H&S §150202 (Amended Stats. 2014, Chapter 10).

On p.12 in item 16.8 (in revised version, item 18.8) delete the citation within the parenthesis "1305.09" and insert "1305.12."

On p.12 in item 16.9 (in revised version, item 18.9), delete the citation within the parenthesis "1305.09" and insert "1305.13."

On p.12, renumber the section heading "**17. After-Hours Supply of Medication**" from number 17 to number **19**.

On p.13, renumber the section heading "**18. Drug Supplies for Use in Medical Emergencies**" from number 18 to number **20**, and renumber the subsequent items sequentially as 20.1, 20.2, 20.3, and 20.4.

On p.13, renumber the section heading "**19. Schedule II-V Controlled Substances Floor Stock Distribution Records**" from number 19 to number **21**.

On p.13, renumber the section heading "**20. Emergency Room Dispensing**" from number 20 to number **22**, and renumber the subsequent items and sub-paragraphs sequentially as 22.1, 22.1.1, 22.1.2, 22.1.3, 22.1.4, 22.1.5, 22.1.6, 22.2, 22.3, 22.4, 22.5, 22.6, and 22.7.

On p.14, renumber the section heading "**21. Discharge Medications/Consultation Services**" from number 21 to number 23, and renumber the subsequent items sequentially as 23.1, 23.2, 23.3, 23.4, 23.5, 23.6, 23.7, 23.8, 23.9, 23.10, 23.11, and 23.12.

On p.15, delete the section heading "**22. Central Fill**" and replace that with the heading "**24. Central Filling of Patient Cassettes For Other Hospital Pharmacies**." Renumber the section from number 22 to number **24**, and renumber the subsequent items sequentially as 24.1, 24.2, 24.3, 24.4, 24.5, 24.6, and 24.7.

On p.16, insert a new section 25 which reads:

25. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 25.1. The pharmacy packages unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

25.1.1. _____ Distance (miles): _____
25.1.2. _____ Distance (miles): _____
25.1.3. _____ Distance (miles): _____
25.1.4. _____ Distance (miles): _____

☐☐☐ 25.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

☐☐☐ 25.3. All unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient's bedside. The barcode information contains: (B&PC 4128.4)

☐ 25.3.1. The date the medication was prepared.

☐ 25.3.2. The components used in the drug product.

☐ 25.3.3. The lot number or control number.

☐ 25.3.4. The expiration date.

☐ 25.3.5. The National Drug Code Directory number.

☐ 25.3.6. The name of the centralized hospital packaging pharmacy.

☐☐☐ 25.4. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. (B&PC 4128.5)

☐☐☐ 25.5. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

These items and sub-paragraphs were based on B&P §4128, 4128.3, 4128.4, 4128.5, 4128.7, all of which were (Added Stats. 2012, Chapter 687),

On p.16, renumber the section heading "**23. Policies and Procedures**" from number 23 to number 26, and renumber the subsequent items sequentially as 26.1, 26.1.1, 26.1.2, 26.1.3, 26.1.4, 26.1.5, 26.1.6, 26.1.7, 26.1.8, and 26.1.9. Should this end up taking up more than one page, please take out any "Yes No N/A" that is not labeling the uppermost boxes on the page, and add in a "Yes No N/A" over the uppermost boxes at the top of each new page.

On p.16, renumber the section heading "**24. Compounding**" from number "24" to number "**27."**

Form 17M-26 The Board proposes the following changes be made in Form 17M-26 "*Wholesalers of Dangerous Drugs and Devices Self-Assessment.'* The proposed changes below both remove out of date material and add new sections, items, and subparagraphs. The changes result in renumbering subsequent pages and items. To simplify locating the proposed changes, all page references refer to the page of the form revised as of 01/11 (no matter how long that page would become due to added items), and item numbers are referred to by the original item number from the 01/11 revision, followed in parenthesis by the new item number as proposed in these amendments.

On every page of Form 17M-26, the footer at the bottom left corner which reads "17M-26 (Rev. 01/11)" should be changed to read "17M-26 (Rev. 10/14)."

On p.1 in the first sentence, delete "18" after the phrase "explained on page" and insert "21."

On p.1 four lines into the form, where the line reads "Wholesaler E-mail address (optional)" delete the word in the parenthesis: "(optional)."

On p.1 underneath the line which reads "DEA Registration #" and "Expiration Date: _____" insert a line that reads: "VAWD Accreditation #_____Expiration Date_____." Two lines below that, where the line begins with "Hours:" strike the word "Daily" and replace it with the word "Weekdays." After the line which begins "DRIC License #" insert a line that reads: "Website Address (optional): _____"

On p.3 in item 1.2, where there is a citation to regulations in parenthesis, move "CCR" from the end of the line to directly in front of "1780(f)(3)" so the citation is all together on one line and easier to read.

On p.4, at item 2.6, move the number "2.6" over to the right so it is not lined up with the boxes, and the number and the words are separated only by two spaces. Thus, delete "2.6" over boxes and insert "2.6" in front of the words of that item.

On p.4 in sub-paragraph 2.6.3, where there is a citation to regulations in parenthesis, move "CCR" from the end of the line to be directly in front of "1780(c)(2)" so the citation is together on one line and easier to read. Also correct the indentation for the last line so it aligns with the line above it.

On p.5, below item 2.9, in the "Note:" just above Section 3, after the phrase "these additional requirements are in Section " change the section number "11" to "12."

On p.5, in item 3.2, after the phrase "… designated representative-in-charge" add the words "at least 18 years of age and is" before the phrase "responsible for the wholesaler's …"

This item was based on B&P 4160 (Amended Stats. 2014, Chapter 507).

On p.6, at item 5.2, delete the “Yes No N/A” above the boxes. Add a section 5.3, with response boxes without “Yes No N/A” on top which reads:

☐☐☐ 5.3. For license verification, the wholesaler may use the licensing information displayed on the board’s Internet web site (B&PC 4106).

This item was based on B&P 4106 (Amended Stats.2005, Chapter 621), and was added at the request of our field inspectors.

On p.6, in the “Note:” after section 5, in the phrase “these additional requirements are in Section 11“ change the section number from “11” to “12.”

On p.7, in the “Note:” after section 6, in the phrase “these additional requirements are in Section 11“ change the section number “11” to “12.”

On p.8 in the “Note:” after section 7, in the phrase “these additional requirements are in Section 11“ change the section number “11” to “12.”

On p.8, at 8.6, insert three boxes to the left of the numbered item, and insert “Yes No N/A” above the boxes.

On p.9, in item 8.10, delete the entire sentence “Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.”

This item was based on B&P §4163 (Repealed and Added Stats. 2014, Chapter 492).

On p.10, at item 8.12, delete the “Yes No N/A” above the boxes. Throughout the document, the “Yes No N/A” above the 3 boxes is to be only above the first set of boxes on a page, over the first set of boxes under a new section, and over the first set of boxes underneath lines for the DRIC to fill in information.

On p.10, at item 8.14, delete the “Yes No N/A” above the boxes.

On p.10, in the “Note:” after section 8, in the phrase “these additional requirements are in Section 11“ change the section number “11” to “12.”

On p.10, insert a new section “**9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204) “** which reads,

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

☐☐☐ 9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

Yes No N/A

☐☐☐ 9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

☐ 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])

☐ 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

These items and sub-paragraphs were based on H&S §150200 (Amended Stats. 2012, Chapter 709), H&S §150203, and H&S §150204 (Amended Stats. 2014, Chapter 155).

On p.10, renumber the section "**9. Outgoing Shipments of Drugs**" from "9" to "10" and re-number the subsequent items sequentially as 10.1, 10.2, and 10.3.

On p.11, in the "Note:" after item 9, in the phrase "… these additional requirements are in Section 11" change the section number "11" to "12."

On p.11, renumber the section "**10. Delivery of Drugs**" from "10" to "11" and renumber the subsequent items sequentially as 11.1, 11.2, 11.3 and 11.4.

On p. 11, at the end of item 10.2 (the revised version, item 11.2), where the citation is in parenthesis, correct the citation to read "B&PC 4059.5[d]"

On p.11, renumber the section "**11. Controlled Substances**" from "11" to "12" and renumber the subsequent items sequentially as 12.1, 12.2, and 12.3, and remove "Yes No N/A" above the boxes for item 11.4 (the revised version, item 12.4) from above the boxes for consistency.

On p.12, after 11.5 (the revised version, item 12.5) insert a new item 12.6 which reads:

☐☐☐ 12.6 Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of Business. (CFR 1304.11)

This item was based on 21 Code of Federal Regulations §1304.11 (79 FR 53562, Sept. 9, 2014).

On pps.12, 13, 14 and 15 renumber the subsequent items of the old section 11 as items 12.5, 12.6, 12.7, 12.8, 12.9, 12.10, 12.11, 12.12, 12.13, 12.14, 12.15, 12.16, 12.17, 12.18, 12.19, 12.20, 12.21, 12.22, 12.23, 12.24, 12.25, 12.26, 12.27, 12.28, and 12.29. As this spans several pages, please take out any "Yes No N/A" that is not labeling the uppermost boxes on the page, and add in a "Yes No N/A" over the uppermost boxes at the top of each page.

On p.13, in item 11.14 (the revised version, item 12.14) delete the underline between "diversion of controlled substances.' and the citation in parenthesis.

On p.13, item 11.19 (the revised version, item 12.19), after the phrase "close of that month?" Delete "(CFR 1309.13(b))" and insert "(CFR 1305.13(b))"

On p.13, item 11.21 (the revised version 12.21) insert a citation in parenthesis "(CFR 1305.21, 1305.22)".

On p.13, item 11.23 (the revised version, item 12.23), delete the citation to "CFR 1305.09[d]" and insert the citation CFR 1305.17 [c]. Delete "H & S" and insert "H&SC".

On p.14, item 11.27 (the revised version, item 12.27) delete the citation "(CFR 1305.16)" and insert the citation "(CFR 1305.17[d])".

On p.14, renumber the section heading "**12. Policies and Procedures**" from "12" to "**13"** and renumber the subsequent items and sub-paragraphs sequentially as 13.1, 13.1.1, 13.1.2, 13.1.3, 13.1.4, 13.1.5, 13.1.6, 13.1.7, 13.1.8, 13.1.9, 13.1.10, 13.1.11, and 13.1.12. Should this end up taking up more than one page, please take out any "Yes No N/A" that is not labeling the uppermost boxes on the page, and add in a "Yes No N/A" over the uppermost boxes at the top of each new page.

On p. 14, in item 12.1 (the revised version, item 13.1) after "policies and procedures for:" insert the citation in parenthesis "(CCR 1780[f])"

On p. 14, sub-paragraph 12.1.7 (the revised version, sub-paragraph 13.1.7) take out the question mark "?" after the phrase "correcting errors?" and insert "and inaccuracies in inventories?" *This was added at the request of our field inspectors.*

On p.15, renumber the section heading "**13. Training**" from "13" to "**14"** and delete the first word "Is" and insert the word "Are".

On p.15, renumber the section heading "**14. Dialysis Drugs**" from "14" to "**15**" and renumber subsequent items sequentially as 15.1, 15.2, 15.3, 15.4. and 15.5.

On p.16, renumber the section heading "**15. Record Keeping Requirements**" from "15" to "**16**"

and renumber the subsequent items sequentially as 16.1,16.2, 16.3, 16.4, 16.5, 16.6, 16.7, 16.8, 16.9, 16.10, 16.11, 16.12, 16.13, 16.14, and 16.15,

On p.16, delete “Yes No N/A” over the boxes at 15.8 (the revised version, item 16.8).

On p.17, delete “Yes No N/A” over the boxes at 15.13 (the revised version, item 16.13).

On p.17, at the “Note:” in the phrase “these additional requirements are in Section 11“ change the section number from “11” to “12.”

On p.17, renumber the section heading “**16. Reporting Requirements to the Board**” from “16” to “**17**” and renumber subsequent items sequentially as 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10, and 17.11.

On p.19, renumber the section heading “**17. Additional Licenses/Permits Required**” from “17” to “**18.**” At section 17, insert item numbers “17.1” in front of the item there.

Underlying Data:

1. January 27-28, 2015, Meeting of the Board of Pharmacy, see Meeting Materials, Legislation and Regulation Committee Report, within attachments at page 34 and page 37.
2. October 29-30, 2014, Meeting of the Board of Pharmacy, see Minutes, pages 9-10, and attachments to the Legislation and Regulation Committee Report, at pages 163 to 264.
3. July 30-31, 2013, Meeting of the Board of Pharmacy, see Meeting Materials, Legislation and Regulation Committee, Regulations Report, attachment 2, pages 13 to 87.
4. July 30, 2013, Legislation and Regulation Committee Meeting, Meeting Materials, page 4, and 2 and attachments thereto from page 135 to page 208.
5. 21 United States Code 829,
6. 21 United States Code 802
7. 21 Code of Federal Regulations §1304.11 et seq.,
8. 21 Code of Federal Regulations 1306.04(b)
9. 21 Code of Federal Regulations 1306.05
10. 21 Code of Federal Regulations 1306.08
11. 21 Code of Federal Regulations 1306.11 et seq.
12. 21 Code of Federal Regulations 1311
13. **Business & Professions Code** §4016.5 (Added Stats. 3013, Chapter469) SB 493 (2013-2014)
14. 4052.6 (Added Stats. 2013, Chapter 469) SB 493 (2013-2014)
15. 4064.5 (Amended Stats. 2012, Chapter 455) SB 1301 (2011-2012)
16. 4067 (Amended Stats. 2003, Chapter 250) SB 175 (2003-2004)
17. 4074 (Amended Stats. 2013, Chapter 304) AB 1136 (2013-2014)
18. 4081 (Amended Stats. 2014, Chapter 507) AB 2605 (2013-2014)
19. 4104 (Amended Stats. 2011, Chapter 646) SB 431 (2011-2012)

20. 4106 (Amended Stats. 2005, Chapter 621) SB 1111 (2005-2006)
21. 4115 (Amended Stats. 2014, Chapter 319) SB 1039 (2013-2014)
22. 4115.5 (Amended Stats. 2005, Chapter 621) SB 1111 (2005-2006)
23. 4119 (Amended Stats. 2010, Chapter 653) SB 1489 (2009-2010)
24. 4119.3 (Added Stats. 2013, Chapter 725) SB 669 (2013-2014)
25. 4128 (Added Stats. 2012, Chapter 687) AB 377 (2011-2012)
26. 4145.5 et seq., (Amended Stats. 2014, Chapter 331) AB 1743 (2013-2014)
27. 4160(a), (Amended 2014, Chapter 507) AB 2605 (2013-2014)
28. 4169 (Amended 2014, Chapter 507) AB 2605 (2013-2014)
29. 4210 (added Stats 2013, Chapter 469) SB 493 (2013-2014)
30. **Health & Safety Code** §1206 (Amended Stats 2005, Chapter 135) SB 47 (2005-2006)
31. 1265 (Amended Stats. 2005, Chapter 507 AB 330 (2005-2006)
32. 11159.2 (Stats. 2005, Chapter 487) SB 734 (2005-2006)
33. 11165.1 et seq. (Stats. 2013, Chapter 400) SB 809 (2013-2014)
34. 11167.5 (Stats. 2003, Chapter 406) SB 151 (2003-2004)
35. 125286.10 et seq. (Stats 2012, Chapter 75) AB 389 (2011-2012)
36. 150200 - Stat, (2012, Chapter 709) SB 1329 (2011-2012)
37. 150201et seq. (2014, Chapter 10) AB 467 (2013-2014)
38. 150202 et seq. (Stats. 2014, Chapter 10) AB 467 (2013-2014)
39. 150202.5 et seq. (Stats, 2012, Chapter 709) SB 1329 (2011-2012)
40. 150203 (Stats 2005, chapter 444 SB 798 (2005-2006)
41. 150204 et seq. (Stats. 2014, Chapter 155) AB 1727 (2013-2014)
42. 22 CCR §70263 et seq. (Title 22- Social Security, section on Pharmaceutical Services General Requirements)

The Board did not rely upon any technical, theoretical or empirical studies in revising the self-assessment forms. The Board's field inspectors have reported to the Board about issues that have arisen during field inspections, and requested certain additions. Additionally, seven members of the Board are pharmacists with a high degree of familiarity with the everyday practice of pharmacy. While not a formal study, the Board's field inspectors consistently tell the Board that completing the self-assessment forms helps PICs and DRICs stay in compliance with relevant laws and regulations.

Business Impact: This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the fact that Board already requires pharmacists and wholesalers to complete certain self-assessment forms every two years, and when triggered by certain circumstances. The Board finds that correcting and updating the laws and regulations cited in the self-assessment forms will have no negative impact on businesses, and may possibly have a positive impact, by helping PICs and DRICs comply with laws and regulations enacted since the last amendment of the forms in 2011.

Economic Impact Assessment:

This regulatory proposal will have the following effects:

-It will not create or eliminate jobs in the State of CA because PICs and DRICs are already required to complete self-assessment forms biennially as of July 1 of every odd-numbered year and upon triggering conditions. The proposed amendments allow the Board to remove superseded or deleted laws and regulations, and add in citations to new laws and regulations.

- It will not create new business or eliminate existing businesses within California because the proposed amendments merely update self-assessment forms PICs and DRICs are already required to complete.

-It would not affect the expansion of businesses currently doing business in California because all PICs and DRICs are required to follow all applicable laws and regulations regardless, but these updated self-assessments will help keep them apprised of what are the laws and regulations adopted since the last amendment of the forms in 2011.

-This regulatory proposal benefits the health and welfare of California residents because having pharmacies and wholesalers follow all applicable laws and regulations helps insure the safety, quality and proper tracking of controlled substances.

-This regulatory proposal benefits worker safety because having pharmacies and wholesalers follow all applicable laws and regulations makes the pharmacies and wholesale sites safer places to work.

-This regulatory proposal does not affect the state's environment because it simply brings up to date mandatory forms the PICs and DRICs already must complete biennially.

Specific Technologies or Equipment: This regulation would not mandate the use of specific technologies or equipment.

Consideration of Alternatives: The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies and other provisions of law.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected by the Board.

Alternative number 1: Draft a new, separate supplementary self-assessment that PICs and DRICs would complete alongside the existing self-assessment. Issuing separate "update" self-assessments is not the most effective means of informing PICs and DRICs of changes in the laws and regulations. While PICs and DRICs would be instructed to strike out any now invalid sections of the last formally revised self-assessment forms, this might not get done, and then the older form would be rendered inaccurate and misleading. Regardless, having two or three part self-assessment forms would be very cumbersome for PICs and DRCs to complete for minimal additional benefit. Issuing updates as separate documents defeats the purpose of having the self-assessment act as an easy reference guide for PICs and DRICs. Adding

additional separate documents increases the record-keeping burden placed on PICs and DRICs.

Alternative number 2: Continue to post updated versions of the self-assessment forms on the Board's website, without going through the formal rulemaking process. Having both the original revision, which was adopted through the rulemaking process, along with the most up-to-date revision of the self-assessment forms, available on the Board's website, can cause confusion. While the most recent form may appear to be the obvious choice, the self-assessment forms are incorporated by reference in 16 CCR §1715 and 16 CCR §1784, a reference which includes the latest revision date (Rev. 01/11). This makes it unclear to PICs and DRICs whether they must use the self-assessment with the revision date cited in the statute, or the updated version. PICs and DRICs who fill out the older formally-adopted form will not be informed of recent changes to the law and regulations, and may fall out of compliance. A part of how the Board meets its mandate to serve the public and increase public safety is by providing PICs and DRICs with updated self-assessments that serve as a summary of all relevant laws and regulations, including those adopted, superseded or deleted, since the last amendment of the forms in 2011.

Title 16. Board of Pharmacy
Proposed Language

Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self- assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self- Assessment" and on Form 17M-14 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

Amend Section 1784 in Article 10 of Division 17 of Title 16 to read:

§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 ~~(Rev. 01/11)~~ (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

FDA News Release

FDA issues new draft documents related to compounding of human drugs

Documents include draft guidances on outsourcing facility registration; outsourcing facility adverse event reporting; drug repackaging; mixing, diluting, and repackaging biological products; and a draft Memorandum of Understanding with the states

For Immediate Release

February 13, 2015

Release

Today, the U.S. Food and Drug Administration issued five draft documents related to drug compounding and repackaging that will help entities comply with important public health provisions. The draft documents are applicable to pharmacies, federal facilities, outsourcing facilities and physicians.

The new category of outsourcing facilities was created under the Drug Quality and Security Act (DQSA), enacted by Congress in November 2013 in response to a deadly fungal meningitis outbreak that was linked to contaminated sterile compounded drug products. Drugs compounded in an outsourcing facility that meet certain conditions may be entitled to exemptions from certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including the new drug approval requirements and the requirement to label drug products with adequate directions for use. Outsourcing facilities are subject to current good manufacturing practice requirements and inspections by the FDA according to a risk-based schedule.

Drugs produced by compounders that are not registered as outsourcing facilities must meet certain other conditions described in the FD&C Act, or they will be subject to all of the requirements applicable to drugs produced by conventional drug manufacturers.

"The draft guidance documents provide information to pharmacies, outsourcing facilities, health care entities, and others about these FDA-proposed policies, which are critical to protecting the public health," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

The documents are:

- **Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434171.pdf)**

The draft guidance provides an entity considering whether to register with the FDA as an outsourcing facility under the law with information about the regulatory impact of registering. For example, it explains that a facility engaged in only certain activities, including repackaging human drugs and compounding non-sterile drugs, should not register as an outsourcing facility because its drug products will not qualify for the exemptions provided in section 503B, including the exemption from the new drug approval requirements.

- **Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf)**
  The draft guidance describes the conditions under which the FDA does not intend to take action for certain violations of the law when state-licensed pharmacies, federal facilities or outsourcing facilities repackage certain drug products. Repackaging generally involves taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container. Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs, and the compounding provisions of the FD&C Act do not address repackaging. Therefore, the FDA is issuing guidance to describe how it intends to address repackaging when done in a state-licensed pharmacy, federal facility, or outsourcing facility.

- **Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434176.pdf**
  The draft guidance describes the conditions under which the FDA does not intend to take action for violations of certain sections of the Public Health Service Act (PHS Act) and the FD&C Act when state-licensed pharmacies, federal facilities or outsourcing facilities mix, dilute or repackage specific biological products without an approved BLA, or when such facilities or physicians prepare prescription sets of allergenic extracts (used to treat allergies) without an approved BLA. The draft guidance notes that a biological product that is mixed, diluted or repackaged outside the scope of an approved BLA is an unlicensed biological product under section 351 of the PHS Act and may not be legally marketed without an approved BLA. Additionally, the compounding provisions of the FD&C Act do not address biological products subject to licensure under section 351 of the PHS Act. Therefore, the FDA is issuing guidance to describe how it intends to address these practices.

- **Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf**
  Entities registered as outsourcing facilities are required to report adverse events to the FDA. The draft guidance explains adverse event reporting for outsourcing facilities.

- **Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM434233.pdf)**
  The draft MOU under section 503A of the FD&C Act describes the responsibilities of a state that chooses to sign the MOU in investigating and responding to complaints related to compounded human drug products distributed outside the state, and in addressing the interstate distribution of "inordinate amounts" of compounded human drug products.

These documents are the latest in a series of policy documents related to FDA oversight of drugs produced by state-licensed pharmacies, federal facilities and outsourcing facilities.

The draft guidance documents are available for public comment for 90 days. The public has 120 days to comment on the draft MOU between the states and the FDA.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Christopher Kelly (mailto:christopher.kelly@fda.hhs.gov)
301-796-4676

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Related Information

- Questions and Answers Related to Guidance For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm434250.htm)
- FDA: Compounding (http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm)

More in Newsroom (/NewsEvents/Newsroom/default.htm)

For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2015
Procedural

For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
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10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 8855-543-3784 or 301-796-3400; Fax: 301-431-6353
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance[1]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or the Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for entities considering whether to register with the Food and Drug Administration (FDA or Agency) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2]

FDA has received questions about whether entities engaged in various types of activities (e.g., a facility that is compounding only non-sterile drugs or only repackaging biological products) should register as an outsourcing facility. Because entities that register as outsourcing facilities in fiscal year (FY) 2015 (beginning October 1, 2014) must pay a registration fee and FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, FDA is issuing this guidance to answer some of these questions and to provide potential registrants additional information about the regulatory impact of registering as an outsourcing facility.

Separate FDA guidance documents contain details on the process for registering as an outsourcing facility[3] and explain how outsourcing facilities should report the products they compound to FDA.[4]

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] A new section 503B was added to the FD&C Act by the Drug Quality and Security Act (DQSA). See Pub. L. No.113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

[3] See draft guidance for industry *Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

All FDA guidances are available on the FDA guidance Webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Drug Quality and Security Act, signed into law on November 27, 2013, creates a new section 503B of the FD&C Act. Section 503B(d)(4) defines an outsourcing facility as

> a facility at one geographic location or address that— (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section.

Section 503B(d)(4) further states that an outsourcing facility is not required to be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients.[5] Section 503B(d)(5) defines *sterile drug* as a "drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law."

A human drug product compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility can *qualify for exemptions* from the drug approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1). However to qualify, each of the following conditions must be met.

1. The outsourcing facility must be in compliance with the registration and reporting requirements of section 503B(b). This includes submitting twice yearly reports regarding the drugs compounded by the outsourcing facility and submitting adverse event reports in accordance with section 503B(b)(5).[6,7]

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[4] See draft guidance for industry *Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

[5] Although an outsourcing facility may send prescription drugs to healthcare facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

[6] See section 301(ccc)(3) of the FD&C Act, which makes it a prohibited act for an entity that is registered in accordance with section 503B(b) to fail to report drugs or adverse events as required.

[7] See sections 503B(a)(1) and (b).

2. If the outsourcing facility compounds drugs using one or more bulk drug substances, the bulk drug substances must meet certain requirements.[8]
3. If the outsourcing facility compounds using ingredients other than bulk drug substances, those ingredients must meet certain requirements.[9]
4. The outsourcing facility must not compound drugs that appear on a list published by FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective.[10,11]
5. The outsourcing facility must not compound drugs that are essentially a copy of one or more approved drugs.[12]
6. The outsourcing facility must not compound drugs that appear on a list published by FDA of drugs that present demonstrable difficulties for compounding.[13]
7. If the outsourcing facility compounds from a drug that is the subject of a risk evaluation and mitigation strategy (REMS) approved with elements to assure safe use pursuant to section 505-1, or from a bulk drug substance that is a component of such drug, the outsourcing facility must demonstrate to FDA before beginning to compound that it will use controls comparable to the controls applicable under the REMS.[14]
8. The outsourcing facility's compounded drugs will not be sold or transferred by an entity other than that outsourcing facility.[15]
9. The outsourcing facility has paid all applicable establishment and reinspection fees owed under section 744(k).[16,17]
10. The outsourcing facility must include on the labels and labeling of its compounded drug products the information required under section 503B(a)(10).[18]

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[8] See section 503B(a)(2).

[9] See section 503B(a)(3).

[10] See section 503B(a)(4).

[11] The list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective (the withdrawn-or-removed list) can be found at 21 CFR 216.24. On July 2, 2014, FDA published a proposed rule that would update that list (Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, 79 FR 37,687). In the preamble to the proposed rule, FDA explained that FDA is proposing to revise and update the withdrawn-or-removed list at 21 CFR 216.24 for purposes of both sections 503A and 503B. Until the final rule revising and updating the withdrawn-or-removed list is published, drugs included on the existing list at 21 CFR 216.24 may not be compounded under section 503B.

[12] See section 503B(a)(5).

[13] See section 503B(a)(6).

[14] See section 503B(a)(7).

[15] See section 503B(a)(8).

[16] See section 503B(a)(9).

[17] See also sections 744J and 744K of the FD&C Act, and guidance for industry Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.

[18] See section 503B(a)(10).

11. The outsourcing facility must compound all drugs in accordance with section 503B.[19]

Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements, among other requirements under the FD&C Act.[20,21] In addition, outsourcing facilities will be inspected by FDA on a risk-based schedule.[22]

III. GUIDANCE

If you register a facility as an outsourcing facility, you are indicating your intent for the facility's compounded drugs to be regulated under section 503B of the FD&C Act. Under section 503B(a)(11), a compounded drug can only qualify for the exemptions from sections 502(f)(1), 505, and 582 of the FD&C Act if ***all*** of the facility's compounded drugs are compounded in accordance with section 503B. As stated above, drugs compounded in accordance with section 503B are not exempt from CGMP requirements, and outsourcing facilities will be inspected by FDA on a risk-based schedule.

If you do not intend to compound ***all*** drugs at your facility in accordance with section 503B and comply with CGMP requirements, you should not register as an outsourcing facility under section 503B.[23] In addition, entities considering registering as outsourcing facilities should consider the following:

- To meet the definition of an *outsourcing facility*, the facility must be engaged in the compounding[24] of sterile human drugs.[25]
- The definition of *compounding* in section 503B(d)(1) does not include repackaging.
- For purposes of section 503B, a drug, including a sterile drug, does not include a biological product subject to licensure under section 351 of the Public Health Service Act (PHS Act), or an animal drug subject to approval under section 512 of the FD&C Act.[26]

[19] See section 503B(a)(11).

[20] FDA has issued a draft guidance for industry *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.* Once finalized, that guidance will represent the Agency's thinking on this topic.

[21] See section 503B(a).

[22] See section 503B(b)(4).

[23] If an entity is not registered as an outsourcing facility under section 503B, its drugs could qualify for the exemptions from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act, if they meet all of the conditions of section 503A. Otherwise, the drugs would be subject to all of the requirements in the FD&C Act applicable to drugs made by conventional manufacturers.

[24] Section 503B(d)(1) defines the term *compounding*, for purposes of that section, to include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

[25] See section 503B(d)(4).

[26] In addition, for purposes of section 503A of the FD&C Act, the term *drug* does not include a biological product subject to licensure under section 351 of the PHS Act.

Therefore, you should ***not*** register a facility as an outsourcing facility if the ***only*** activities conducted at the facility are repackaging, compounding non-sterile or animal drugs, or mixing, diluting, or repackaging biological products subject to licensure under section 351 of the PHS Act because ***none of the products produced at the facility would qualify for the exemptions provided in section 503B***.

In addition, by registering as an outsourcing facility, an entity is electing to have its compounded drugs regulated under section 503B of the FD&C Act, not section 503A. Drugs compounded at an outsourcing facility are not eligible for the exemptions provided in section 503A, even if the conditions in that section are met with respect to the particular drug.

FDA is issuing separate draft guidances on (1) mixing, diluting, and repackaging biological products outside the scope of an approved biologics license application and (2) repackaging certain human drug products by pharmacies and outsourcing facilities. These guidance documents will describe FDA's compliance policies with respect to biological products that are mixed, diluted, or repackaged outside the scope of an approved biologics license application (BLA) and repackaged human drugs.

If a facility compounds sterile human drugs and otherwise meets the definition of an outsourcing facility, any non-sterile human drugs compounded by the facility would also be eligible for the exemptions from sections 505, 502(f)(1), and 582 if the drugs are compounded in accordance with the provisions of section 503B. However, if a facility that meets the definition of an outsourcing facility repackages certain human drugs, or mixes, dilutes, or repackages biological products outside the scope of an approved BLA, FDA does not intend to take action against those products for violations of certain provisions of the FD&C Act or the PHS Act, if applicable, provided those products satisfy the conditions described in the two guidances on biological products and repackaging, referenced above.

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Gail Bormel, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC), at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

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Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

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Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
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February 2015
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Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities[1]
Guidance for Industry[2]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's ("FDA" or "the Agency") policy regarding repackaging by state-licensed pharmacies, Federal facilities, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and where specified, section 501(a)(2)(B) of the Act, when a state-licensed pharmacy, a Federal facility, or an outsourcing facility repackages human prescription drug products.

This guidance **does not address** the following:

- Biological products that are subject to licensure under section 351 of the Public Health Service (PHS) Act. The repackaging of biological products subject to licensure under section 351 is addressed in a separate draft guidance document.[3]

[1] "Outsourcing facility" refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the Federal Food, Drug, and Cosmetic Act.

[2] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[3] FDA has issued a draft guidance, titled *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* Once finalized, that guidance will represent FDA's thinking on this topic.

All FDA guidances are available on the Agency's guidance website at http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

- Repackaging drug products for use in animals. FDA will consider addressing this issue in a separate guidance document.
- Repackaging by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities. See additional information in section III.A. of this draft guidance document.
- Removing a drug product from the original container at the point of care for immediate administration to a single patient after receipt of a patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA does not consider this to be "repackaging," for purposes of this guidance document.
- Upon receipt of an individual patient-specific prescription, a licensed pharmacy removing from one container the quantity of solid oral dosage form drug products necessary to fill the prescription and placing it in a smaller container to dispense directly to its customer.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Repackaging, Generally

FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

Repackaging is performed by a range of entities, including facilities that specialize in repackaging drug products, and pharmacies, including pharmacies in hospitals and health systems. FDA is aware that repackaging is done for a variety of reasons including: to meet the needs of specific groups of patients (e.g., pediatric patients or ophthalmic patients who require smaller doses of approved sterile drug products that may not be available commercially); to reduce medication errors associated with drawing up a dose from a vial at the point of patient care; to reduce the availability of drug products of abuse when controlled substances are left over in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular device to administer the drug (such as a particular pain medication pump); for convenience for the practitioner administering an injection to a patient; and in some cases to reduce cost. Some repackagers repackage both sterile and non-sterile drug products. For example, tablets and capsules are repackaged from large containers into smaller containers or blister packs, and creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or containers.

As part of the drug application review and approval process, FDA evaluates the container closure system and the packaging into which the drug will be placed, as well as the conditions under which the drug will be packaged. The container closure system and packaging can affect the quality of the drug product when it is on the market. In particular, during the approval process FDA reviews whether the container closure system and the packaging are appropriate for maintaining the stability of the drug product through its expiration date, as long as the container and package are not breached, and the drug is stored according to the conditions specified in the application. For drug products required to be sterile, FDA also considers whether the container closure system and packaging are adequate to ensure that the drug product will remain sterile until its expiration date, as long as the container closure is not breached and the drug product is stored appropriately.

When a drug product is repackaged, its characteristics may change in ways that have not been evaluated during the FDA approval process and that could affect the safety and efficacy of the drug product. Improper repackaging of drug products can cause serious adverse events. Of particular concern is repackaging of sterile drug products, which are susceptible to contamination and degradation. For example, failure to properly manipulate sterile drug products under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling could result in drug product degradation and adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated.

B. Regulatory Framework for Repackaging

Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. For example, repackaged drug products are generally subject to the premarket approval, misbranding, and adulteration provisions of the FD&C Act, including section 505 (concerning new drug applications),[4] section 502(f)(1) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)).

Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act.[5] Therefore, drug products repackaged by state-licensed pharmacies, Federal facilities, or outsourcing facilities are not eligible for the exemptions provided under those sections. In this

[4] But see U.S. v. Kaybel, 430 F.2d 1346 (3d Cir. 1970) (holding that repackaging of approved Enovid (estrogen) tablets from large bottles into small bottles did not require pre-approval under section 505 of the FD&C Act).

[5] Section 503A of the FD&C Act exempts compounded drug products from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act provided certain conditions are met, including that the drug product is compounded pursuant to a prescription for an individually identified patient from a licensed practitioner. The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act and the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act if the conditions in section 503B are met. Drug products compounded in outsourcing facilities are not exempt from the CGMP requirements of section 501(a)(2)(B).

guidance, FDA describes the conditions under which it does not intend to take action regarding violations of certain requirements of the FD&C Act, in the context of drug repackaging.

C. Hospital and Health System[6] Repackaging of Drugs In Shortage For Use in the Health System (Section 506F of the FD&C Act)

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in July, 2012, added section 506F to the FD&C Act. This section exempts certain hospitals within a health system from registration requirements in section 510 of the Act provided certain conditions are met, including that the drugs are, or have recently been, listed on FDA's drug shortage list[7] and are repackaged for the health system. Section 506F of the FD&C Act defines "repackaging," for purposes of that section only, as "divid[ing] the volume of a drug into smaller amounts in order to—(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list under section 506E; and (B) facilitate access to the drug by hospitals within the same health system."

Section 506F of the FD&C Act has a termination clause that states "This section [506F] shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage."[8] These issues are addressed and clarified by this guidance and the guidance on *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. Therefore, when these guidances become final, section 506F of the FD&C Act will no longer apply.

III. POLICY

A. General Policy

As discussed above, repackaged drug products are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act.[9] FDA does not intend to take action for violations of sections 505 and 502(f)(1) if a state-licensed pharmacy, a Federal facility, or an

[6] For purposes of this guidance, the term *"health system"* refers to a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

[7] See section 506F(b) (providing that the exemption may be available if, among other factors, the drug is repackaged (1) during any period in which the drug is listed on the drug shortage list under section 506E; or (2) during the 60-day period following any period described in paragraph (1)).

[8] See section 506F(d) of the FD&C Act.

[9] As described in section II.B., repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. Therefore, drug products that do not meet the conditions in this guidance, including drug products repackaged by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities, generally must comply with requirements in the FD&C Act and FDA regulations applicable to drug products including, but not limited to, CGMP and new drug approval requirements.

outsourcing facility repackages drug products in accordance with the conditions described below, and any applicable requirements.[10] In addition, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act if the drug product is repackaged by a state-licensed pharmacy or a Federal facility in accordance with the conditions described below, and any applicable requirements.

The conditions referred to in the preceding paragraph are as follows:

1. The drug that is being repackaged is a prescription drug product approved under section 505 of the FD&C Act, except as provided in section III.B of this guidance regarding repackaging unapproved drug products that appear on FDA's drug shortage list under section 506E.

2. The drug product is repackaged in a state-licensed pharmacy, a Federal facility, or an outsourcing facility.

3. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility (but not an outsourcing facility), it is repackaged and distributed[11] after (a) the receipt of a valid prescription for an identified, individual patient directly from the prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart in a health care setting, unless it is repackaged (but not distributed) in advance of receipt of such a prescription or a written order in a patient's chart in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy or the Federal facility repackaged pursuant to patient-specific prescriptions or written orders in a previous, consecutive 14-day period, and based on a history of receipt of prescriptions or written orders over a consecutive 14-day period for such repackaged drug products.

4. The drug product is repackaged by or under the direct supervision of a licensed pharmacist.

5. Except as provided below for a single-dose vial, the drug product is repackaged in a way that does not conflict with approved drug product labeling.[12]

   For a single-dose vial that is repackaged into multiple units, the drug product is repackaged in a way that does not conflict with the approved labeling, except for the

[10] Applicable requirements include, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

[11] Distribution means that the repackaged drug product has left the facility in which it was repackaged.

[12] For example, if the approved labeling contains instructions for handling or storage of the product, the repackaging is done in accordance with those instructions. Otherwise, it would be considered to be in conflict with the approved labeling.

statements designating the product as a single dose or single use product, and related language (e.g., discard remaining contents).[13]

6. The repackaged drug product is assigned a beyond-use-date (BUD)[14] as described below:

   a. **FDA-approved drug product with a specified in-use time**: If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling a time within which the opened product is to be used (an "in-use" time), the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.[15]

   b. **FDA-approved drug product without an in-use time or unapproved drug product**: If the drug product being repackaged is an FDA-approved drug product whose labeling does not specify an in-use time, or if it is an unapproved drug product on the FDA drug shortage list (which does not have an in-use time reviewed by FDA as part of the drug approval process), the repackaged drug product is assigned a BUD (1) that is established in accordance with the time described in (i) or (ii) below, as applicable, or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.[16]

      i. **Sterile Drug Products:** The repackaged drug product is assigned a BUD no longer than the following, even if the time until the expiration date on the drug product being repackaged is longer:

         1. If repackaged in a state-licensed pharmacy or Federal facility, the repackaged drug product is assigned a BUD that is[17]:

[13] This condition would not be satisfied if a drug product repackaged from a single-dose vial is repackaged in a way that conflicts with other language in the approved labeling (e.g., regarding storage conditions).

[14] Unless otherwise indicated, the BUD timeframes in this condition begin from the time in which the container of the original drug product to be repackaged is punctured or otherwise opened.

[15] For example, if an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2015 on the label is repackaged on January 1, 2015, the applicable BUD for the repackaged drug product would be January 4, 2015, because the labeled in-use time of 3 days is shorter than the time until the labeled expiration date of the drug product (14 days). If the drug product is repackaged on January 14, 2015, the applicable BUD for the repackaged drug product would be January 15, 2015, because the time until the labeled expiration date of the approved drug product is 1 day, which is shorter than the labeled 3-day in-use time.

[16] In other words, if the FDA-approved drug product does not have an in-use time, or the drug product being repackaged is an unapproved drug product, the times in (i) and (ii) are the default BUDs, unless the expiration date on the drug product being repackaged is shorter, in which case the BUD would be the same as the expiration date.

[17] These BUDs are consistent with the BUDs established by USP Chapter <797> for "medium-risk" compounded sterile preparations. Although USP <797> addresses *compounded* sterile preparations, many of the same principles for conditions and practices to assure sterility and stability of compounded drug products, such as the requirement to maintain a sterile environment, engage in appropriate sterile processing techniques, and put appropriate BUDs on the product, also apply to repackaged sterile drug products to help ensure their quality is not compromised during

- ≤ 30 hours if stored at USP controlled room temperature;
- ≤ 9 days if stored in a refrigerator; or
- ≤ 45 days if stored in a solid frozen state between -25°C and -10°C

2. **If repackaged in an outsourcing facility,** the outsourcing facility conducts a sterility test in accordance with CGMP requirements[18] (e.g., using the sterility test described in USP Chapter <71>) and receives passing results before release, and the repackaged drug product is assigned a BUD that is[19]:

- Not more than 14 days beyond completion of the sterility test or 28 days from the time of repackaging, whichever is shorter, if stored at USP controlled room temperature or in a refrigerator; or
- Not more than 45 days beyond completion of the sterility test or 59 days from the time of repackaging, whichever is shorter, if stored in a solid frozen state between -25°C and -10°C[20]

ii. **Non-sterile Drug Products:** The BUD for the repackaged drug product is no longer than the expiration date on the original drug product being repackaged.

7. Except with regard to BUDs, which are addressed in condition 6, above:
   a. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility:
      i. If it is a non-sterile drug product, it is repackaged in accordance with USP Chapter <795>; or

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and after the repackaging operation. The BUDs for medium-risk compounded preparations in USP <797> are appropriate for sterile drug products that do not include an "in-use" time and are repackaged by a state-licensed pharmacy or Federal facility because the two activities present comparable risks.

[18] See 21 CFR part 211.

[19] These longer BUDs reflect that outsourcing facilities must comply with CGMP requirements and are subject to FDA inspections on a risk-based schedule. Conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility. FDA has issued a draft guidance entitled, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* ("Interim CGMP Guidance"). (See http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf) The Interim CGMP Guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated. The BUDs set forth for sterile drug products repackaged by outsourcing facilities in this condition are consistent with the BUDs listed in the Interim CGMP Guidance that are applicable to sterile drug products compounded at outsourcing facilities.

[20] The 28-day and 59-day timeframes provide for the 14 days it takes to receive results from the sterility test conducted under USP Chapter <71>.

ii. If it is sterile drug product, it is repackaged in accordance with USP Chapter <797>, e.g., a sterile drug product is repackaged in an area with air quality that meets or exceeds ISO Class 5 standards (see USP Chapter <797>, Table 1).

b. If the drug product is repackaged in an outsourcing facility, repackaging is conducted in accordance with CGMP requirements.

8. The drug product that is being repackaged does not appear on a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or ineffective. For purposes of this provision, repackagers should refer to the list of drug products in 21 CFR 216.24, developed for use with sections 503A and 503B.

9. The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.

10. The repackaged drug product is distributed only in states in which the facility repackaging the drug product meets all applicable state requirements.

11. If the drug product is repackaged by an outsourcing facility:

    a. The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes the following:
        i. The statement "This drug product was repackaged by [name of outsourcing facility]"
        ii. The address and phone number of the outsourcing facility that repackaged the drug product
        iii. The established name of the original, approved drug product that was repackaged
        iv. The lot or batch number of the repackaged drug product
        v. The dosage form and strength of the repackaged drug product
        vi. A statement of either the quantity or volume of the repackaged drug product, whichever is appropriate
        vii. The date the drug product was repackaged
        viii. The BUD of the repackaged drug product
        ix. Storage and handling instructions for the repackaged drug product
        x. The National Drug Code (NDC) number of the repackaged drug product, if available[21]
        xi. The statement "Not for resale," and, if the drug product is distributed by an outsourcing facility other than pursuant to a

[21] The NDC number of the original approved drug product should not be placed on the repackaged drug product.

prescription for an individual identified patient, the statement "Office Use Only"

xii. If included on the label of the FDA-approved drug product from which the drug product is being repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below in 11.b.i.

b. The label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the repackaged products are distributed) includes:
    i. The active and inactive ingredients, if the immediate drug product label is too small to include this information
    ii. Directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

c. Each repackaged drug product is also accompanied by a copy of the prescribing information that accompanied the original drug product that was repackaged.

d. The drug product is included on a report submitted to FDA each June and December identifying the drug products made by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.[22]

e. The outsourcing facility reports serious adverse events to FDA that may be associated with its repackaged drug products.

B. Repackaging Drugs on FDA's Drug Shortage List

This guidance addresses repackaging of prescription drug products, including drug products on FDA's drug shortage list, by a state-licensed pharmacy, Federal facility, or outsourcing facility, including within a hospital or health system. This guidance also specifically addresses the repackaging of single-dose vials, a practice that is sometimes used to extend the supply of a drug

[22] FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the Agency's current thinking on that topic. Although that guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the drug products they repackaged.

product that is on the FDA drug shortage list. In addition, the first condition described in section III.A.1 of this guidance provides that the drug product being repackaged is a prescription drug product approved by FDA under section 505 of the FD&C Act. However, with respect to an unapproved drug product that appears on FDA's drug shortage list, FDA also does not intend to take action for violations of sections 505, 502(f)(1), and, as specified above, section 501(a)(2)(B), provided that the state-licensed pharmacy, the Federal facility, or the outsourcing facility (including within a hospital or health system) meets all of the conditions of this guidance, and the repackaged drug product is distributed during any period in which the drug product is listed on the drug shortage list under section 506E of the FD&C Act or during the 30 days following such period. As stated above, this guidance and the guidance on *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* clarify the Agency's policy regarding hospital pharmacies repackaging and safely transferring repackaged drug products to other hospitals within the same health system during a drug shortage. Therefore, when these guidances become final, section 506F of the FD&C Act will no longer apply.

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Leah Christl (CDER) at 301-796-0869 or the Office of Communication, Outreach, and Development (CBER) at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2015
Compliance

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

Guidance for Industry

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Food and Drug Administration
10903 New Hampshire Ave., Building 71, Room 3128
Silver Spring, MD 20993
Phone: 800-835-4709 or 240-402-7800
Email: ocod@fda.hhs.gov
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry[1]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or the Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION AND SCOPE

This guidance sets forth FDA's policy regarding the mixing,[2] diluting, and repackaging[3] of certain types of biological products that have been licensed under section 351 of the Public Health Service Act (PHS Act) when such activities are not within the scope of the product's approved biologics license application (BLA) as described in the approved labeling for the product.[4] This guidance describes the conditions under which FDA does not intend to take action for violations of sections 351 of the PHS Act and sections 502(f)(1) and where specified, section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when a state-licensed pharmacy, a Federal facility, or an outsourcing facility[5] dilutes, mixes or repackages certain biological products without obtaining an approved BLA.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in cooperation with the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] For purposes of this guidance, mixing means combining an FDA-licensed biological product with one or more ingredients. Not covered by this guidance is diluting or mixing a biological product at the point of care for immediate administration to a single patient after receipt of a patient specific prescription or order for that patient (e.g., diluting or mixing into a syringe to administer directly to the patient).

[3] For purposes of this guidance, repackaging means taking a licensed biological product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. As used in this guidance, the terms mixing, diluting, and repackaging describe distinct sets of activities with respect to a biological product.

[4] This guidance does not apply to blood and blood components for transfusion, vaccines, cell therapy products, and gene therapy products

[5] *"Outsourcing facility"* refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. *See* FDA's draft guidance, *"Guidance for Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act."*

This guidance **does not address** the following:

- Biological products not subject to licensure under section 351 of the PHS Act (i.e., biological products for which a marketing application could properly be submitted under section 505 of the FD&C Act (see section 7002(e) of the Affordable Care Act)). The repackaging of biological products not subject to licensure under section 351 is addressed in a separate draft guidance document. [6]
- Products intended for use in animals. FDA will consider addressing this issue in a separate guidance document.
- Mixing, diluting, or repackaging biological products (other than allergenic extracts) by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities; and preparation of allergenic extracts by entities that are not state-licensed pharmacies, Federal facilities, outsourcing facilities, or physicians (See additional information in section III.A. of this draft guidance document).
- Removing a biological product from the original container at the point of care for immediate administration to a single patient after receipt of a patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA does not consider this to be "repackaging," for purposes of this guidance document.
- Upon receipt of a patient-specific prescription, a licensed pharmacy removing from one container the quantity of solid oral dosage form biological products necessary to fill the prescription and placing it in a smaller container to dispense directly to its customer.
- Mixing, diluting, or repackaging a licensed biological product when the product is being mixed, diluted, or repackaged in accordance with the approved BLA as described in the approved labeling for the product. FDA considers this to be an approved manipulation of the product.
- Mixing, diluting, or repackaging of blood and blood components for transfusion,[7] vaccines, cell therapy products, or gene therapy products (see footnote 4). The guidance does not alter FDA's existing approach to regulating the collection and processing of blood and blood components. In addition, FDA intends to consider regulatory action if licensed vaccines, cell therapy products, and gene therapy products are subject to additional manufacturing, including mixing, diluting, or repackaging, in ways not specified in the product's approved BLA as described in the approved labeling for the product.

As stated above, this guidance does not address the mixing, diluting, or repackaging of a biological product for which a marketing application could properly be submitted under section 505 of the FD&C Act (see section 7002(e) of the Affordable Care Act). Accordingly, the term

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[6] The repackaging of biological products approved under section 505 is addressed in a separate draft Guidance, "*Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.*"

[7] The guidance does apply to licensed biological products that are plasma derived products, including recombinant and transgenic versions of plasma derivatives, mixed, diluted, or repackaged outside the scope of an approved BLA.

"biological product" as used in this guidance does not include products for which a marketing application can be or has been submitted under section 505 of the FD&C Act.

Section II of this guidance provides background on biological products and the legal framework for FDA's regulation of these products, and explains that sections 503A and 503B of the FD&C Act do not provide exemptions for mixing, diluting, or repackaging of biological products. Section III describes FDA's policy on mixing, diluting, or repackaging of certain licensed biological products that is not within the scope of the product's approved BLA as described in the approved labeling for the product.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Biological Products

The term "biological product" is defined in section 351(i)(1) of the PHS Act to mean:

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Biological products can be complex chains or combinations of sugars, amino acids, or nucleic acids, or living entities such as cells and cellular therapies. Biological products include therapeutic proteins, monoclonal antibodies, allergenic extracts, blood and blood derivatives, cell therapy products, and gene therapy products, preventive vaccines, and therapeutic vaccines. Generally, biological products have a complex set of structural features (e.g., amino acid sequence, glycosylation, folding) essential to their intended effect, and are very sensitive to changes to their manufacturing process, including, but not limited to, any manipulation outside of their approved container-closure systems. In addition, many biological products are particularly sensitive to storage and handling conditions and can break down or aggregate if exposed to heat and/or light, if dropped, or if shaken during storage and handling. Accordingly, diluting or mixing a biological product with other components, or repackaging a biological product by removing it from its approved container-closure system and transferring it to another container-closure system, is, in the absence of manufacturing controls, highly likely to affect the safety and/or effectiveness of the biological product.

Nevertheless, certain licensed biological products may need to be mixed or diluted in a way not described in the approved labeling for the product to meet the needs of a specific patient. For example, for some biological products there is no licensed pediatric strength and/or dosage form, so the product must be diluted for use in pediatric patients. In addition, there may be certain

circumstances where a person would repackage a licensed biological product by removing it from its original container and placing it into a different container(s), in a manner that is not within the scope of the approved BLA as described in the approved labeling for the product. Like other drugs, biological products are sometimes repackaged for various reasons including for pediatric or ophthalmic use. For example, a pediatric dialysis unit may repackage a larger quantity of a product into smaller aliquots so that the optimal dose may be administered to each pediatric dialysis patient being treated at that particular time.

Repackaging a drug or biological product could change its characteristics in ways that have not been evaluated during the approval process and that could affect the safety and effectiveness of the product. Improper repackaging of drug and biological products can cause serious adverse events. Of particular concern is the repackaging of sterile drugs, which are susceptible to contamination and degradation. For example, failure to properly repackage a sterile drug under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling have led to product degradation resulting in adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated. These risks are often even more acute for biological products due to their complex composition and sensitivity to variations in storage and handling conditions.

Cell and gene therapy products often contain viable cells or intact/active viral vectors. The manufacturing process for these products is complex and includes multiple controls to assure the purity or potency of the product and its safety and effectiveness. Many cell therapy products are cryopreserved, and the procedures for thawing and handling in preparation for administration described in the approved labeling must be followed to maintain the safety and effectiveness of the product. In addition, because these products are frequently implanted or administered intravenously and are not typically amenable to terminal sterilization, their microbiological safety is dependent largely on facility design, aseptic technique, and manufacturing protocols that are best controlled by robust quality systems.

Vaccines are manufactured using biological systems and supplied by manufacturers in single dose or multi-dose presentations. Unlike most other drugs and biological products, vaccines are administered to healthy individuals, including infants, to prevent disease. Vaccines may contain live attenuated organisms, inactivated organisms, or components of bacteria or viruses such as polysaccharides, inactivated toxins, or purified proteins. The manufacturing process for vaccines is complex and includes multiple controls to assure safety and effectiveness. Each single dose of a vaccine is formulated to deliver the correct quantity of active ingredient(s) to the recipient.

The policies in this guidance do not cover cell therapy products, gene therapy products, and vaccines. Because of the particularly sensitive nature of these products as described above, these categories of products must be prepared, and if applicable to that product's use, repackaged, under an approved BLA, in accordance with section 351 of the PHS Act.

The policies in this guidance also do not cover or alter FDA's existing approach to regulating the collection and processing of blood and blood components for transfusion. These activities are

currently conducted in FDA licensed or registered blood collection establishments and in hospital-based transfusion services regulated in part by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988. In all instances, blood collection and processing is already subject to current good manufacturing practices (CGMP) under the existing statutory and regulatory framework for blood and blood components and will not be subject to the policies described here.

B. Legal Framework for FDA's Regulation of Biological Products

Section 351(a)(1) of the PHS Act prohibits the introduction into interstate commerce of any biological product unless "a biologics license…is in effect for the biological product." For FDA to approve a BLA, the BLA must contain data to demonstrate that the biological product is safe, pure, and potent and that the facility in which the biological product will be manufactured, processed, packed, or held meets standards designed to ensure that the biological product continues to be safe, pure, and potent. Because manufacturing controls are so important to ensuring the safety and effectiveness of biological products, FDA licensing of a biological product is based, in part, on an extensive review of chemistry and manufacturing controls data submitted by the applicant. This includes a thorough evaluation of the raw materials, drug substance, and drug product to ensure consistency in manufacturing and continued safety and effectiveness. In addition, other data are submitted and reviewed (e.g., stability and compatibility testing results) to establish the storage and handling conditions appropriate to ensure the safety, purity, and potency of the biological product.

A biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is an *unlicensed biological product* under section 351 of the PHS Act. For example, if a licensed biological product is diluted or mixed with components other than those described in the approved labeling for the product, or if it is removed from its original container-closure system and placed in a new container-closure system that is not described in the approved labeling for the product, these additional manufacturing steps would create a new, unlicensed biological product. To be legally marketed, the new biological product would have to be licensed on the basis of an approved BLA that includes, among other things, chemistry and manufacturing controls data.

C. Sections 503A and 503B of the FD&C Act Do Not Exempt Biological Products from the Premarket Approval Requirements of the PHS Act or from Provisions of the FD&C Act

Section 503A of the FD&C Act exempts compounded drugs from sections 505 (concerning new drug approval of human drugs products), 502(f)(1) (concerning labeling of drug products with adequate directions for use), and 501(a)(2)(B) of the FD&C Act (concerning CGMP) provided that certain conditions are met, including that the drug is compounded pursuant to a prescription for an individually-identified patient from a licensed practitioner.

The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA. Drug products compounded under the direct supervision of a licensed pharmacist in an

outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act and the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act if the conditions in section 503B are met. Drugs compounded in outsourcing facilities are not exempt from the CGMP requirements of section 501(a)(2)(B).

Although sections 503A and 503B provide an exemption for certain compounded drugs from the requirement to obtain premarket approval under section 505 of the FD&C Act, they do not provide an exemption from the requirement to obtain premarket approval under section 351 of the PHS Act. Manufacturers of biological products must obtain an approved license under section 351(a) or (k) of the PHS Act. Thus, for purposes of sections 503A and 503B, a *drug* does not include any biological product that is subject to licensure under section 351 of the PHS Act. Accordingly, such biological products are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FD&C Act. In other words, the FD&C Act does not provide a legal pathway for marketing biological products that have been prepared outside the scope of an approved BLA.

D. Hospital and Health System[8] Repackaging of Drugs In Shortage For Use in the Health System (Section 506F of the FD&C Act)

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in July, 2012, added section 506F to the FD&C Act. This section exempts certain hospitals within a health system from registration requirements in section 510 of the Act provided certain conditions are met, including that the drugs (including biological products) are, or have recently been, listed on FDA's drug shortage list[9] and are repackaged for the health system. Section 506F of the FD&C Act defines "repackaging," for purposes of that section only, as "divid[ing] the volume of a drug into smaller amounts in order to—(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list under section 506E; and (B) facilitate access to the drug by hospitals within the same health system."

Section 506F of the FD&C Act has a termination clause that states "This section [506F] shall not apply on or after the date on which the Secretary issues a final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs [including drugs that are licensed biological products] to other hospitals within the same health system during a drug shortage." [10] These issues are addressed and clarified by this guidance, and the guidance on *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*. Therefore, when these guidances become final, section 506F of the FD&C Act will no longer apply.

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[8] For purposes of this guidance, the term *"health system"* refers to a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

[9] See section 506F(b) (providing that the exemption may be available if, among other factors, the drug is repackaged (1) during any period in which the drug is listed on the drug shortage list under section 506E; or (2) during the 60-day period following any period described in paragraph (1)).

[10] See section 506F(d) of the FD&C Act.

III. POLICY

Because biological products sometimes need to be mixed, diluted, or repackaged in ways not addressed in labeling approved for the product under section 351 of the PHS Act, but do not qualify for the exemptions in sections 503A or 503B of the FD&C Act, FDA has developed this guidance to explain the conditions under which FDA does not intend to take action when certain biological products are mixed, diluted, or repackaged in a manner not described in their approved labeling.

A. General Conditions

This guidance addresses the mixing, diluting, or repackaging of a licensed biological product, not a biological product licensed for further manufacturing use only, or a bulk drug substance. The policies expressed in this guidance do not extend to any person or entity that mixes, dilutes, or repackages a biological product from any other starting material. Consistent with section 351 of the PHS Act, a manufacturer seeking to mix, dilute, or repackage a biological product licensed for further manufacturing use only, or a bulk drug substance, must first submit a BLA and obtain a license for the product.

Furthermore, the policies expressed in this guidance apply only to the mixing, diluting, or repackaging of certain licensed biological products, in accordance with the conditions specified in sections III.B and III.C of this guidance. Except as described in sections III.B and III.C, the agency will consider regulatory action if a licensed biological product is subject to additional manufacturing, including mixing, diluting, or repackaging, outside of the conditions specified in the approved labeling for the licensed product.

As described in section B, a biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is an unlicensed biological product under section 351 of the PHS Act. To be legally marketed, the new biological product would have to be licensed on the basis of an approved BLA, have labeling with adequate directions for use, and be made in accordance with biological product standards and CGMP requirements. Therefore, biological products that do not meet the conditions in this guidance, including 1) biological products that are mixed, diluted, or repackaged by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities or 2) prescription sets of allergenic extracts that are not prepared by state-licensed pharmacies, Federal facilities, outsourcing facilities, or licensed physicians, must comply with requirements in the PHS Act, FD&C Act, and FDA regulations applicable to biological products manufactured by "conventional" manufacturers, including, but not limited to, biological product license requirements, and compliance with applicable standards and CGMP requirements.

B. Mixing, Diluting, or Repackaging Licensed Biological Products

FDA does not intend to take action for violations of sections 351 of the PHS Act or 502(f)(1) of the FD&C Act if a state-licensed pharmacy, a Federal facility, or an outsourcing facility[11] mixes, dilutes, or repackages a biological product in accordance with the conditions described below, and any applicable requirements.[12] In addition, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act when a state-licensed pharmacy or a Federal facility mixes, dilutes, or repackages a biological product in accordance with the conditions described below, and any applicable requirements. Outsourcing facilities remain subject to applicable CGMP requirements.

The conditions referred to in the preceding paragraph are as follows:

1. The biological product that is mixed, diluted, or repackaged is an FDA-licensed biological product, not a biological product licensed for further manufacturing use only or a bulk drug substance.

2. The biological product is mixed, diluted, or repackaged in a state-licensed pharmacy, a Federal facility, or an outsourcing facility.

3. If the biological product is mixed, diluted, or repackaged in a state-licensed pharmacy or a Federal facility (but not an outsourcing facility), it is mixed, diluted, or repackaged after (a) the receipt of a valid prescription for an identified, individual patient directly from the prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart in a healthcare setting,[13] unless it is mixed, diluted, or repackaged (but not distributed) in advance of receipt of such a prescription or a written order in a patient's chart in a quantity that does not exceed the expected demand for the biological product within the beyond use date (BUD) on the product, based on a history of receipt of prescriptions or orders for such a biological product for that time period.

4. The biological product is mixed, diluted, or repackaged by or under the direct supervision of a licensed pharmacist.

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[11] As we discuss in section II of this guidance, biological products licensed under section 351 of the PHS Act are not eligible for the statutory exemptions offered by sections 503A or 503B of the FD&C Act, and if a facility registers as an outsourcing facility but only mixes, dilutes, or repackages such biological products, none of the products made at the facility will be eligible for the exemptions under section 503B. However, this guidance describes the conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and sections 501(a)(2)(B) and 502(f)(1) of the FD&C Act if such biological products are mixed, diluted, or repackaged at a state-licensed pharmacy, a Federal facility, or an outsourcing facility that compounds drug products in accordance with section 503B.

[12] Applicable requirements include, for example, the requirement that manufacturers not adulterate a biological product by preparing, packing , or holding the drug under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

[13] Drugs produced by outsourcing facilities, including drugs that are also biological products, remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, a prescription drug, including a biological product, cannot be dispensed to a patient without a prescription.

5. Except as provided below for a single dose vial, the biological product is mixed, diluted, or repackaged in a way that does not conflict with the approved labeling for the licensed biological product.[14]

   For a biological product packaged in a single dose vial that is mixed, diluted, or repackaged into multiple units, the biological product is mixed, diluted, or repackaged in a way that does not conflict with the approved labeling, except for the statements designating the product as a single dose or single use product, and related language (e.g., discard remaining contents).[15]

6. As described in section II of this guidance, biological products are very susceptible to product quality concerns when mixed, diluted, or repackaged. For example, because biological products provide a rich media for microbial growth, they are particularly susceptible to microbial proliferation over time, if contaminated. Therefore, the mixed, diluted, or repackaged biological product is given a BUD that is not longer than the applicable BUD[16] below:

   a. If the biological product is mixed, diluted, or repackaged by a state-licensed pharmacy or a Federal facility, it is given a BUD that
      - is not longer than 4 hours, or is equal to the time within which the opened product is to be used as specified in the approved labeling, whichever is shorter; [17] or

      - is up to 24 hours if microbial challenge studies performed on the formulation of the diluted, mixed, or repackaged biological product in the type of container in which it will be packaged demonstrate that microbial growth will not progress to an unacceptable level within the period of the BUD. (See Appendix 1 for a description of microbial challenge study design.)

   b. If the biological product is mixed or diluted by an outsourcing facility, it is given a BUD that

[14] For example, if the approved labeling for the licensed biological product contains instructions for handling or storage of the product, the mixing, diluting, or repackaging is done in accordance with those instructions. Otherwise, it would be considered to be in conflict with the approved labeling for the licensed biological product.

[15] For example, Avastin (bevacizumab) is packaged in a single dose vial. This condition could be satisfied even if Avastin is repackaged into multiple single dose syringes despite the fact that the label of the approved product states, "Single-use vial…Discard unused portion." However, this condition would not be satisfied if Avastin is mixed, diluted, or repackaged in a manner that conflicts with other language in the approved labeling (e.g., regarding the appropriate diluent and storage conditions).

[16] The BUD timeframes in this condition begin from the time in which the container of the original biological product to be repackaged or to be used for mixing or diluting is punctured or otherwise opened ("opened product").

[17] The 4 hour BUD timeframe in this guidance is consistent with the labeling of many licensed biological products, which require the disposal of any product not used within 4 hours after the product has been reconstituted or the container has been entered. Where another timeframe is provided in the labeling, it is based on data generated under specific conditions by the product's manufacturer and submitted with the BLA. Such data are not available for products mixed, diluted, or repackaged outside the scope of a BLA, as described in this guidance.

- is not longer than 4 hours, or is equal to the time within which the opened product is to be used as specified on the approved labeling, whichever is shorter; or

- is up to 24 hours if microbial challenge studies performed on the formulation of the mixed or diluted biological product in the type of container in which it will be packaged demonstrate that microbial growth will not progress to an unacceptable level within the period of the BUD. (See Appendix 1 for a description of microbial challenge study design.)

c. If the biological product is repackaged by an outsourcing facility, it is given a BUD that
   - is not longer than 4 hours, or is equal to the time within which the opened product is to be used as specified on the approved labeling, whichever is shorter; or

   - is up to 24 hours if microbial challenge studies performed on the formulation of the repackaged biological product in the type of container in which it will be packaged demonstrate that microbial growth will not progress to an unacceptable level within the period of the BUD. (See Appendix 1 for a description of microbial challenge study design); or

   - does not exceed 5 days or the expiration date of the biological product being repackaged, whichever is shorter, provided that the outsourcing facility conducts adequate compatibility studies on the container-closure system (e.g., the syringe) of the repackaged biological product to demonstrate compatibility and ensure product integrity. (*See* Title 21, section 211.94 of the Code of Federal Regulations for regulations on drug product containers and closures). [18]

7. If the biological product is mixed, diluted, or repackaged in a state-licensed pharmacy or a Federal facility, it is done in accordance with the United States Pharmacopeia (USP) Chapter <797>, except the BUD is as specified in condition 6; if the biological product is mixed, diluted, or repackaged in an outsourcing facility, it is done in accordance with CGMP requirements, except the BUD is as specified in condition 6.

8. The biological product is not sold or transferred by an entity other than the entity that mixed, diluted, or repackaged the biological product. For purposes of this condition, a sale or transfer does not include administration of a biological product in a health care setting.

[18] This longer BUD reflects that outsourcing facilities must comply with CGMP requirements and are subject to FDA inspections on a risk-based schedule. Conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility. This longer BUD is not provided for mixed or diluted biological products because these activities are more likely to alter the characteristics of the biological product in ways that could harm patients, even if performed under CGMP conditions. To provide a sufficient basis for FDA to conclude that a longer BUD on a mixed or diluted product was justified, an outsourcing facility would need to submit a BLA that included data on the impacts of diluting or mixing the specific product.

9. The mixed, diluted, or repackaged biological product is distributed only in states in which the facility mixing, diluting, or repackaging the biological product meets any applicable state requirements.

10. If the biological product is mixed, diluted, or repackaged by an outsourcing facility:

    a. The label on the immediate container (primary packaging, e.g., the syringe) of the mixed, diluted, or repackaged biological product includes the following:
        i. The statement "This biological product was mixed/diluted by [name of outsourcing facility]," or "This product was repackaged by [name of outsourcing facility]", whichever statement is appropriate
        ii. The address and phone number of the outsourcing facility that mixed, diluted, or repackaged the biological product
        iii. The proper name of the original biological product that was mixed, diluted, or repackaged
        iv. The lot or batch number assigned by the outsourcing facility for the mixed, diluted, or repackaged biological product
        v. The dosage form and strength of the mixed, diluted, or repackaged biological product
        vi. A statement of either the quantity or the volume of the mixed, diluted, or repackaged biological product, whichever is appropriate
        vii. The date the biological product was mixed, diluted, or repackaged
        viii. The BUD of the mixed, diluted, or repackaged biological product
        ix. Storage and handling instructions for the mixed, diluted, or repackaged biological product
        x. The National Drug Code (NDC) number of the mixed, diluted, or repackaged biological product, if available[19]
        xi. The statement "Not for resale," and, if the biological product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"
        xii. If included on the label of the FDA-licensed biological product from which the biological product is being mixed, diluted, or repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below in 10.b.i; and if the biological product is mixed or diluted, the label of the mixed or diluted product includes any ingredients that appear in the mixed or diluted product in addition to those ingredients that are on the original FDA-licensed biological product.

    b. The label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed) includes:

[19] The NDC number of the original licensed biological product should not be placed on the mixed, diluted, or repackaged biological product.

i. The active and inactive ingredients, if the immediate product label is too small to include this information
ii. Directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

c. Each mixed, diluted, or repackaged biological product is also accompanied by a copy of the prescribing information that accompanied the original FDA-licensed biological product that was mixed, diluted, or repackaged.

d. The mixed, diluted, or repackaged biological product is included on a report submitted to FDA each June and December identifying the drug products made by the outsourcing facility during the previous 6-month period, including: a notation that this is a mixed, diluted, or repackaged biological product; the active ingredient; the source of the active ingredient; NDC number of the source ingredient, if available; strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units mixed, diluted, or repackaged[20]; and the NDC number of the final product, if assigned.[21]

e. The outsourcing facility reports serious adverse events to FDA that may be associated with its mixed, diluted, or repackaged biological products.

C. Licensed Allergenic Extracts

FDA recognizes that there are circumstances in which licensed allergenic extracts would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products. Such combinations are commonly referred to as prescription sets.[22] For the purpose of this guidance a *prescription set* is defined as a vial or set of vials of premixed licensed standardized and non-standardized allergenic extracts for subcutaneous immunotherapy diluted with an appropriate diluent prepared according to instructions from a prescription or order by a licensed physician for an individual patient.

[20] Currently, FDA's electronic drug reporting system is not configured to accept additional information that is specific to biological products, such as license number. In the future, FDA intends to modify the system to accept this information.

[21] FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* , which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the biological products they mixed, diluted, or repackaged.

[22] Under 21 CFR 610.17, licensed biological products must not be combined with other licensed biological products; either therapeutic, prophylactic or diagnostic, except as covered by a license obtained for the combined product. All mixes of allergenic extracts that are not prescription sets must be the subject of an approved BLA, or have in effect an investigational new drug application.

FDA does not intend to take action for violations of section 351 of the PHS Act or section 502(f)(1) of the FD&C Act if a physician, state-licensed pharmacy, a Federal facility, or outsourcing facility prepares prescription sets of allergenic extracts in accordance with the conditions described below, and any applicable requirements.[23]

In addition, with respect to a prescription set prepared in accordance with the following conditions and any applicable requirements, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act when the prescription set is prepared by a physician, state-licensed pharmacy, or a Federal facility in accordance with the conditions described below; outsourcing facilities remain subject to applicable CGMP requirements.

The conditions referred to in the preceding paragraph are as follows:

1. The prescription set is prepared from FDA-licensed allergenic extracts and appropriate diluents.

2. The prescription set is prepared in a in a physician's office, state-licensed pharmacy, a Federal facility, or outsourcing facility.

3. If the prescription sets are prepared in a physician's office, state-licensed pharmacy, or a Federal facility (but not an outsourcing facility), each set is prepared after (a) the receipt of a valid prescription for an identified, individual patient directly from the prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart, unless it is prepared in advance of receipt of such a prescription or a written order in a quantity that does not exceed the expected demand for that prescription set within the BUD for the product, based on a history of receipt of prescriptions or orders for such a prescription set for that time period. If the prescription sets are prepared in an outsourcing facility, those sets are prepared either after, or in anticipation of, receiving valid prescriptions for an identified, individual patient or a written order in a patient's chart.

4. The prescription set is distributed to a physician or to a health system for use within the health system only after the receipt of a valid prescription for an identified, individual patient or a written order in a patient's chart.

5. The prescription set is prepared in a way that does not conflict with approved labeling of the licensed biological products that are part of the prescription set.[24]

6. The BUD for the prescription set is no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set.

[23] See note 12.
[24] See note 15.

7. If the prescription set is prepared in a state-licensed pharmacy or a Federal facility, or in a physician's office, it is prepared in accordance with USP Chapter <797>, except the BUD is as specified in condition 6; if the prescription set is prepared in an outsourcing facility, it is prepared in accordance with applicable CGMP requirements, except the BUD is as specified in condition 6.

8. The prepared prescription set is not sold or transferred by an entity other than the entity that prepared the prescription set. For purposes of this condition, a sale or transfer does not include administration of a prescription set in a health care setting.

9. The prescription set is distributed[25] only in states in which the facility preparing the prescription set meets any applicable state requirements.

10. If the prescription set is prepared by an outsourcing facility:

    a. The label on the immediate container(s) (primary packaging) of the prescription set includes the following:
        i. The patient's name as identified on the prescription
        ii. The statement "This prescription set was prepared by [name of outsourcing facility]"
        iii. The address, and phone number of the outsourcing facility that prepared the prescription set
        iv. The identity of each allergenic extract in the prescription set, and the quantity of each
        v. The dilution of each dilution vial
        vi. The lot or batch number of the prescription set
        vii. The date the prescription set was prepared
        viii. The BUD of the prescription set
        ix. Storage and handling instructions for the prescription set
        x. The statement "Not for resale"

    b. The label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

    c. Each prescription set also is accompanied by instructions for use and the FDA approved package insert for each allergenic extract.

    d. The prescription set is included in a report submitted to FDA each June and December identifying the drug products made by the outsourcing facility during the previous 6-month period, including: a notation that this is a biological product; the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage

[25] *Distribution* means that the prepared prescription set has left the facility in which it was prepared.

form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.[26]

e. The outsourcing facility reports serious adverse events to FDA that may be associated with its prescription sets.

[26] FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* , which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the Agency's thinking on that topic. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the prescription sets they prepared.

APPENDIX 1 – MICROBIAL CHALLENGE STUDY DESIGN

The following design recommendations for product growth promotion studies should be followed to extend the BUD to up to 24 hours for a mixed, diluted, or repackaged biological product as referenced in Section II. B.

Microbial challenge studies are designed to demonstrate that the product in question does not support adventitious microbial growth under the proposed storage conditions. Each facility would conduct a microbial challenge study at least once for each mixed, diluted, or repackaged biological product, to demonstrate that the microbial quality of the biological product mixed, diluted, or repackaged by that facility can be ensured. The microbial challenge study should be repeated if the formulation or the container-closure system is changed. The studies should be accurately documented and records maintained for inspection.

The challenge microbes should include the panel provided in USP<51> Antimicrobial Effectiveness Testing.[27] These strains represent the species *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans* and *Aspergillus brasiliensis* (formerly *Aspergillus niger*). It should also incorporate typical skin microflora and nosocomial agents to simulate the types of flora that may contaminate a drug product in a healthcare setting. Finally, the challenge should include strains of the tribe *Klebsielleae*, as they have been shown to proliferate in infusion products.[28]

Individual containers of the mixed, diluted, or repackaged biological product should be inoculated with each challenge organism, with each container receiving one type of organism. The inoculum size should be small but also measurable and repeatable. For example, if a membrane filtration method is used to quantify the number of organisms, an inoculum size of fewer than 100 CFU/mL is appropriate.

Following inoculation of the final product with the challenge organisms, the test units should be stored at the temperature(s) described in the biological product's labeling. Samples should be removed periodically throughout the duration of the study for determination of microbial count for up to 72 hours (3 times the maximum BUD). To support a BUD of 24 hours, each challenge organism should demonstrate no increase from the initial count (where *no increase* is defined as not more than 0.5 log10 unit higher than the initial inoculum at any time point up to 72 hours) and no evidence of growth. As explained in the example below, data from a study of 72 hours' duration should be examined for trending and to establish a maximum storage time of up to 24 hours at a specified temperature.

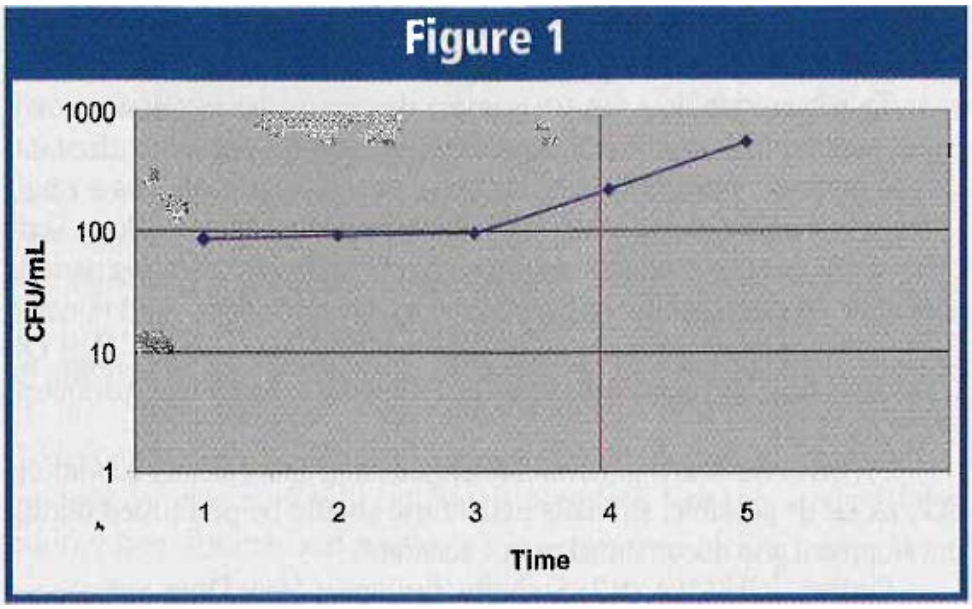
Example: Determination of Microbial Growth

[27] USP51/NF26. United States Pharmacopeial Convention, 2008.
[28] See, Mahl, M.C., et al. Nitrogen Fixation by Members of the Tribe *Klebsielleae*, *J. Bacteriol.*, 1965, 89(6): 1482; Maki, D., et al., Infection Control in Intravenous Therapy, *Annals of Internal Medicine*, 1973, 79: 867.

The following table represents data from a hypothetical microbial challenge experiment where the inoculum is less than 100 CFU/mL, and the requested maximum hold time is equivalent to Time Point 4.

Time	Microbial Count (CFU/mL)	Log of Microbial Count
1	88	1.9
2	95	2
3	98	2
4	220	2.3
5	552	2.7

These data reflect *no increase* from the initial count through Time Point 4. However, as illustrated in Figure 1 below, the semi-logarithmic graph of CFU/mL vs. Time shows clear evidence of growth of the challenge organism at Time Point 4.



Thus, a maximum hold time equivalent to that of Time Point 4 would pose potential risk to the microbiological quality of the hypothetical mixed, diluted, or repackaged biological product, and the acceptable BUD would be set at one-third of Time Point 3. It is also important to note that, if the experiment were concluded at Time Point 4, the ability to predict the trend of the data would be lost. As presented in the graphic, the growth trend appears to signal the start of log-phase growth, which could occur earlier or later with different strains of a given species. Such growth would produce exponential increases in the microbial population that pose significant risk to patients. This concern is the reason for periodic sampling when determining microbial concentration.

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact H. Joy Sharp at 301-796-3647 or Joy.Sharp@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2015
Drug Safety

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

February 2015
Drug Safety

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Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry[1]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or the Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for firms that have registered with the Food and Drug Administration (FDA) under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as human drug compounding outsourcing facilities (outsourcing facilities). Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)."[2] This guidance explains FDA's current thinking on adverse event reporting for outsourcing facilities.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Statutory and Regulatory Framework

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] 21 U.S.C. 353b(b)(5).

On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law. Title I of the DQSA contains important provisions related to the oversight of human drug compounding.[3] The DQSA added section 503B to the FD&C Act. Under section 503B(b), a compounder can register as an *outsourcing facility* with FDA.[4] Under section 503B(b)(5), an outsourcing facility must submit adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)."[5]

Section 310.305 requires, among other things, that manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug application or an abbreviated new drug application establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences[6] associated with the use of their prescription drug products. For purposes of reporting adverse drug experiences, the term *prescription drug products* includes any compounded drug product subject to the prescription requirements in section 503(b)(1) of the FD&C Act. The adverse event reporting requirements apply to prescription drug products regardless of whether the outsourcing facility distributes them pursuant to prescriptions.[7]

In addition, on June 10, 2014, FDA issued a final rule requiring, among other things, that postmarketing safety reports required under 21 CFR 310.305, 314.80, 314.98, and 600.80 be submitted to FDA in an electronic format the Agency can process, review, and archive. The final rule also adds 21 CFR 329.100 to address electronic submission of safety reports required by section 760 of the FD&C Act regarding serious adverse event reporting for nonprescription drugs.[8] These requirements are effective as of June 10, 2015.[9]

Under section 503B, outsourcing facilities are required to submit adverse event reports to FDA, in accordance with content and format requirements established through guidance or regulation under 21 CFR 310.305 (or any successor regulations).

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[3] See text of Compounding Quality Act at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm.

[4] 21 U.S.C. 353b(b).

[5] Id. at 353b(b)(5).

[6] This guidance uses the terms *adverse drug experience* and *adverse event* interchangeably.

[7] Section 503B(d)(4)(C) of the FD&C Act provides that outsourcing facilities may or may not obtain prescriptions for identified individual patients. Although outsourcing facilities may send prescription drugs to healthcare facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

[8] 21 U.S.C. 379aa.

[9] See 79 FR 33072. FDA intends to issue guidance reflecting the requirements of the final rule before they become effective.

Failure to report adverse events by an entity that is registered in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FD&C Act.[10] Violations relating to this provision are subject to regulatory and enforcement action.

B. Section 310.305

Section 310.305(b) defines a *serious adverse drug experience* to mean:

> Any adverse drug experience occurring at any dose that results in any of the following outcomes:
>
> - Death,
> - A life-threatening adverse drug experience,
> - Inpatient hospitalization or prolongation of existing hospitalization,
> - A persistent or significant disability/incapacity, or
> - A congenital anomaly/birth defect
>
> Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include
>
> - allergic bronchospasm requiring intensive treatment in an emergency room or at home,
> - blood dyscrasias or convulsions that do not result in inpatient hospitalization, or
> - the development of drug dependency or drug abuse.

Section 310.305(b) defines an *unexpected adverse drug experience* as any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. The term *unexpected*, as used in this definition, refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling), rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

The regulations require reporting of each adverse drug experience received or otherwise obtained that is both serious and unexpected as soon as possible, but in no case later than 15 calendar days of initial receipt of the information along with a copy of the drug product's current labeling.[11] In addition, all serious, unexpected adverse drug experiences that are the subject of these reports

[10] 21 U.S.C. 331(ccc)(3).

[11] See 21 CFR 310.305(c)(1)(i).

shall be promptly investigated and a follow-up report must be submitted within 15 calendar days of receipt of new information or as requested by FDA.[12]

FDA's regulations also state that information on the names and addresses of individual patients should ***not*** be included.[13] A unique code number should therefore be assigned instead for each individual patient and placed in section A1 of Form FDA 3500A (Patient Identifier).

The regulations require that firms maintain certain records relating to adverse drug experiences required to be reported under section 310.305 for 10 years and provide FDA access to them.[14] The regulations also provide a disclaimer that the report or information submitted (and any release by FDA of that report or information) does not necessarily reflect a conclusion that the report or information constitutes an admission that the drug caused or contributed to an adverse effect.[15]

III. Adverse Event Reporting by Outsourcing Facilities

A. What to Report

Outsourcing facilities must report all serious, unexpected adverse drug experiences associated with the use of their compounded prescription drug products.

In addition, FDA strongly recommends that outsourcing facilities report ***all*** serious adverse drug experiences associated with their compounded prescription drug products. We believe reporting ***all*** serious adverse events would provide important information about potential product quality issues or public health risks associated with drug products compounded by outsourcing facilities.

B. Threshold for Reporting

As noted above, outsourcing facilities must submit to FDA reports of all serious, unexpected adverse events associated with their compounded prescription drugs.[16]

When considering any adverse drug experience for submission to FDA in a report, after receiving information about the adverse drug experience, an outsourcing facility should actively investigate the following four data elements, which are described in greater detail later in this section:

1. An identifiable patient

[12] See 21 CFR 310.305(c)(2).

[13] See 21 CFR 310.305(e).

[14] See 21 CFR 310.305(f).

[15] See 21 CFR 310.305(g).

[16] See 21 CFR 310.305(c).

2. An identifiable reporter
3. A suspect drug
4. A serious adverse event

Although an outsourcing facility should actively seek to obtain each of these four data elements, the facility must submit the report as a *15-day "Alert report"* to FDA as soon as possible, but no later than 15 calendar days after first receiving information about the adverse event.[17] **Reports should be submitted as long as the outsourcing facility has information on at least the suspect drug and the adverse event.**

The outsourcing facility must also promptly investigate adverse events that are the subject of a 15-day "Alert report".[18] If the outsourcing facility was not able to include all four of the data elements in its initial report, it should exercise due diligence to obtain information about any of the remaining elements. Additionally, the outsourcing facility should report new information it obtains regarding data elements listed in its initial report when the information could assist FDA in investigating an adverse event. If additional information is not obtainable, the outsourcing facility should maintain records of the steps that were taken to attempt to seek the additional information.[19]

An outsourcing facility must submit a follow-up report within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA.[20]

1. Identifiable Patient

To have an identifiable patient, there should be enough information to indicate the existence of a specific patient. One or more of the following would qualify a patient as identifiable:

- Age or age category (e.g., adolescent, adult, elderly)
- Gender
- Initials
- Date of birth
- Name
- Patient identification number

A report stating that "an elderly woman had anaphylaxis" or "a young man experienced anaphylaxis" would be sufficient. If a report refers to groups of unknown size, such as "some" or "a few" college students had anaphylaxis, the outsourcing facility should follow up to find out

[17] See 21 CFR 310.305(c)(1)(i).

[18] See 21 CFR 310.305(c)(2).

[19] Id.

[20] Id.

how many students were involved and submit a separate report to FDA for each student, because each is considered to be an identifiable patient. The outsourcing facility should distinguish each identifiable patient so that it is clear that each report is not a duplicate report of a single adverse event.

Patients should not be identified by name or address when reporting to FDA. Instead, the outsourcing facility should assign a unique code number for each patient.[21]

2. Identifiable Reporter

A reporter is a person who initially notifies the outsourcing facility about an adverse event. An initial reporter can be a patient, consumer, family member, doctor, pharmacist, other health care professional, or other individual. The outsourcing facility should obtain, if possible, sufficient information to indicate that the reporter is an identifiable person who purports to have knowledge about the patient, adverse event, and drug involved. One or more of the following would qualify a reporter as identifiable:

- A personal identifier (e.g., name)
- A professional identifier (e.g., doctor, nurse, pharmacist)
- Contact information (e.g., e-mail address, phone number)

When possible, the outsourcing facility should attempt to obtain the initial reporter's contact information so that the outsourcing facility and/or FDA can conduct follow-up investigations. If an identifiable reporter provides contact information, but requests that the outsourcing facility not forward this information to FDA, the outsourcing facility can submit a report to FDA without specifically identifying the reporter by filling out the *initial reporter identity fields* on Form FDA 3500A with a statement such as "Requested Anonymity."

If an adverse event is reported anonymously to an outsourcing facility, the outsourcing facility should note when submitting the report to FDA that the initial reporter is anonymous (section E1 of the Form FDA 3500A).

3. Suspect Drug

A *suspect drug product* is one that the initial reporter suspected was associated with the adverse event.

For reporting purposes, an adverse event report should describe the known product attributes (e.g., active ingredient(s), dosage form, strength, color, lot number). If an adverse event involves multiple suspect drug products that are compounded by the same outsourcing facility, the outsourcing facility should submit only one report that notes the drug product considered most

[21] See 21 CFR 310.305(e).

suspect by the reporter. If the reporter views each drug product as equally suspect, the outsourcing facility should submit only one report that lists all of the drug products as suspect. In all cases, including those where not all of the drug products were made by the outsourcing facility, the report would include information on all suspect drug products.

4. Serious Adverse Event

As described above, outsourcing facilities must report an unexpected adverse event to FDA that results in one or more of the following patient outcomes:

- Death,
- A life-threatening adverse drug experience,
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant disability or incapacity, or
- A congenital anomaly or birth defect.[22]

Inpatient hospitalization includes initial admission to the hospital on an inpatient basis (even if released the same day).

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience if, when based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

The outsourcing facility must report the adverse event to FDA if it is serious and unexpected. For reporting purposes, an adverse event should be described in terms of signs (including abnormal laboratory findings, if appropriate), symptoms, or disease diagnosis (including any colloquial descriptions obtained), if available.

As part of the adverse event report, we encourage, as appropriate, attachment of the following: (1) hospital discharge summaries, (2) autopsy reports/death certificates, (3) relevant laboratory data, and (4) other critical clinical data. In the case of a death, outsourcing facilities should also provide any available information on the event(s) that led to the death.

C. How to Report Adverse Events

Outsourcing facilities must report adverse events using Form FDA 3500A or an alternate method in accordance with 21 CFR 310.305(d) and should submit the report to FDA as described here. FDA is currently modifying its process to specifically identify reports from outsourcing facilities and drug products compounded by outsourcing facilities. Until those actions are completed, FDA will not be able to effectively accept adverse event reports from outsourcing facilities

[22] See 21 CFR 310.305(b).

through the electronic system, but FDA will issue additional guidance when the electronic interface is ready to accept these reports.

1. Obtaining Form FDA 3500A

Outsourcing facilities can access paper copies of Form FDA 3500A as follows:

- Download and print the Form FDA 3500A and instructions from the Internet at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf

- Request a paper copy of Form FDA 3500A and instructions from CDER's Division of Drug Information:

  By e-mail: druginfo@fda.hhs.gov

  By phone: 1-800-FDA-1088
  1-888-INFO-FDA
  1-888-463-6332 or (301) 796-3400

  By mail: Division of Drug Information
  10903 New Hampshire Avenue
  WO51-2201
  Silver Spring, MD 20993-0002

2. How to Submit Adverse Event Reports

Until FDA modifies its adverse event collection database to more effectively accommodate direct electronic submissions from outsourcing facilities, adverse event reports and follow-up reports for compounded drug products should be provided in hard copy.[23] In accordance with section 310.305(c), outsourcing facilities must submit a copy of Form FDA 3500A to:

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

3. What Should Be Included

[23] FDA is currently modifying its database to include fields specifically identifying reports from outsourcing facilities and drug products compounded by outsourcing facilities. As noted above, on June 10, 2014, FDA issued a final rule requiring that, among other things, postmarketing safety reports under 21 CFR 310.305 be submitted to FDA in electronic format (79 FR 33072). This rule is effective as of June 10, 2015.

Outsourcing facilities must indicate whether the report is a 15-day Alert report or a 15-day Alert report-follow-up [24] and should include the following header on the first page of a cover letter accompanying each Form FDA 3500A:

Adverse event report submitted by human drug compounding outsourcing facility (503B)

If the compounded drug product contains multiple components (e.g., excipients, drug substances, finished dosage forms), the outsourcing facility should list each component and its manufacturer, if known, in section C10 of Form FDA 3500A. The outsourcing facility should also list in section C10, in addition to the components of the compounded drug and each component's manufacturer, any other medical product(s) the patient was taking at the time he or she experienced the adverse event and the manufacturer of that product(s) (i.e., any concomitant medical products).

As part of each adverse event report, outsourcing facilities must submit a copy of the current labeling for the compounded drug product that is the subject of the report.[25]

When submitting a follow-up report under 21 CFR 310.305(c)(2), the report should be assigned the same manufacturer report number that appears in section G9 of the initially submitted Form FDA 3500A.

D. Inspection of Adverse Event Reporting

Under section 503B(b)(4) of the FD&C Act, outsourcing facilities are subject to inspection pursuant to section 704 of the FD&C Act and are not eligible for the exemption under section 704(a)(2)(A) of the FD&C Act.

As part of its inspections of outsourcing facilities, FDA may review adverse event information received by the outsourcing facility.[26] FDA may also review whether the outsourcing facility has developed and implemented written processes for the surveillance, receipt, evaluation, and

[24] 21 CFR 310.305(c)(4).

[25] See section 21 CFR 310.305(c)(1)(i).

[26] See section 21 CFR 310.305(f)(3).

reporting of adverse events for the drug products it compounds as described in 21 CFR 310.305(a) and 211.198.[27]

E. Recordkeeping

Under section 310.305, all entities subject to the regulation must maintain for 10 years the records of all adverse events required to be reported under this section, including raw data and any correspondence relating to the adverse event, and allow FDA access to review, copy, and verify these records, in accordance with 21 CFR 310.305(f). In addition, the outsourcing facility should maintain records of its efforts to obtain the four data elements discussed in section III.B. for each individual case report.

[27] Outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements. Pending the development of further regulations, FDA expects outsourcing facilities, among other things, to comply with the CGMP requirements in 21 CFR 211.198, which is a companion to 21 CFR 310.305. This section requires that "[w]ritten procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed," and further requires that these procedures must include "provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with [section] 310.305 … of this chapter." See FDA's guidance for industry, *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf.

DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE STATE OF [insert STATE] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to compounded human drug products distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to drugs that are compounded by registered outsourcing facilities.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

   1. Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

   2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

   3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, among other things, a compounded human drug product must meet the condition in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

   1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts[1] of compounded human drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded human drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

[1]The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy a of commercially available drug product).

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded human drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms with the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. Appropriate agencies of the State of [insert State] will investigate complaints received relating to human drug products compounded by a pharmacist, pharmacy, or physician located in the State of [insert State] and distributed outside the State. Primary responsibility for investigating complaints involving human drug products compounded by a pharmacy or pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency] and similar responsibility for human drug products compounded by a physician will generally lie with the [insert State Medical Licensing Board or other appropriate State agency], except where State laws otherwise require. The [insert State Board of Pharmacy or other appropriate State agency] and [insert State Medical Licensing Board or other appropriate State agency] will cooperate in investigating any complaints involving overlapping jurisdiction.

2. Complaints relating to compounded human drug products distributed outside the State that will be investigated include reports received by the State concerning adverse drug experiences, or product quality issues that if left uncorrected could lead to potential public health risks or safety concerns. See Appendix A for definitions of *adverse drug experiences* and *product quality issues*.

3. Any investigations performed by the State of [insert State] under this MOU will include, but are not limited to (1) determination of whether there is a potential public health risk or safety concern associated with the compounded human drug product; and (2) confirmation that any risk or safety concern associated with the product is adequately contained (i.e., there is no ongoing risk to the public).

4. Based on findings from an investigation of a complaint about compounded human drug products distributed outside the State, if the complaint is found to be valid, the State of [insert State], in accordance with State law, will take appropriate action to ensure that the relevant compounding pharmacist, pharmacy, or physician determines the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to eliminate any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.

5. The State of [insert State] will notify FDA by sending an e-mail to StateMOU@fda.hhs.gov (see section III.c.1 of this MOU) within 72 hours of receiving any complaint relating to a compounded human drug product distributed outside the State involving a public health risk or immediate safety concern, such as a report of a serious adverse drug experience or serious product quality issue. The notification will include the State's initial assessment of the validity of the complaint relating to a compounded human drug product distributed outside the State, as well as a description of any actions the State has taken or plans to take to address such complaints. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue*.

6. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate

1. The State of [insert State] will review compounding records during inspections of compounding pharmacies to identify whether the compounding pharmacy, or the compounding pharmacist or physician, is distributing inordinate amounts of compounded human drug products interstate. See Appendix A for the definition of *distribution*.

2. The State of [insert State] will notify FDA by sending an e-mail to StateMOU@fda.hhs.gov (see section III.c.1 of this MOU) within 7 days of identifying a pharmacist, pharmacy, or physician within its jurisdiction that has distributed inordinate amounts of compounded human drug products interstate.

3. The State of [insert State] will take action regarding any pharmacy, pharmacist, or physician that distributes inordinate amounts of

compounded human drug products interstate. State action may include a warning letter, enforcement action, suspension or revocation of a license, or other action consistent with State law. FDA may also take action regarding any pharmacy, pharmacist, or physician that distributes inordinate amounts of compounded human drug products interstate.

4. For purposes of this MOU, a pharmacist, pharmacy, or physician has distributed an inordinate amount of compounded human drug products interstate if the number of units of compounded human drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such pharmacist, pharmacy, or physician during that month. Exception: For purposes of this MOU, FDA does not intend to include, in the consideration of inordinate amounts, prescriptions dispensed to a patient (or patient's agent), if the patient (or patient's agent) to whom the drug is dispensed carries the drug across State lines after it has been dispensed to the patient (or patient's agent) at the facility in which the drug was compounded.

c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov regarding complaints relating to compounded drug products distributed outside the State or distribution of inordinate amounts of drugs interstate, the following minimum information will be included:

- Name and contact information of the complainant, in the case of a complaint;
- Name and address of the pharmacist/pharmacy/physician that is the subject of the complaint or distribution in inordinate amounts;
- Description of the complaint, or description of the evidence indicating that the pharmacist/pharmacy/physician has distributed inordinate amounts of compounded human drug products interstate, including a description of any compounded drug product that is the subject of the complaint or distribution;
- State's initial assessment of the validity of the complaint relating to a compounded human drug product distributed outside the State; and

- Description and date of any actions the State has taken to address the complaint or the distribution of inordinate amounts of compounded human drug products interstate.

2. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 or commissioning of officials under 21 CFR 20.84 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement, or commissioning terms, will govern FDA's sharing of the following types of information:

    - confidential commercial information, such as the information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

    - personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

    - information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. 1905)), the Privacy Act (5 U.S.C. 552a), other Freedom of Information Act exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

    FDA agrees that information provided to FDA by the State of [insert State] will only be disclosed consistent with applicable federal law and regulations governing the disclosure of such information, including, but not limited to, the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the State of [insert State] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or

prevent the State of [insert State] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the State of [insert State] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the State no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the State will notify FDA.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center of Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
E-mail: StateMOU@fda.hhs.gov

[State]
TBD

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the State does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the State will notify all pharmacists, pharmacies, and physicians within the

State of the termination and advise them that as of 30 days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the licensed pharmacist, licensed pharmacy, or licensed physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR THE STATE OF [insert State]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution:** *Distribution* means that a compounded human drug product has left the facility in which the drug was compounded. Distribution includes delivery or shipment to a physician's office, hospital, or other health care setting for administration and dispensing to an agent of a patient or to a patient for the patient's own use.

  Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

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Eliminating preventable harm and improving the quality of health care delivery

Syringes and infusion lines – big changes ahead

Rory Jaffe, MD MBA

Executive Director

California Hospital Patient Safety Organization (CHPSO)

Member Small Bore Connectors ISO work group

Some illustrations provided courtesy of ASPEN: American Society for Parenteral and Enteral Nutrition

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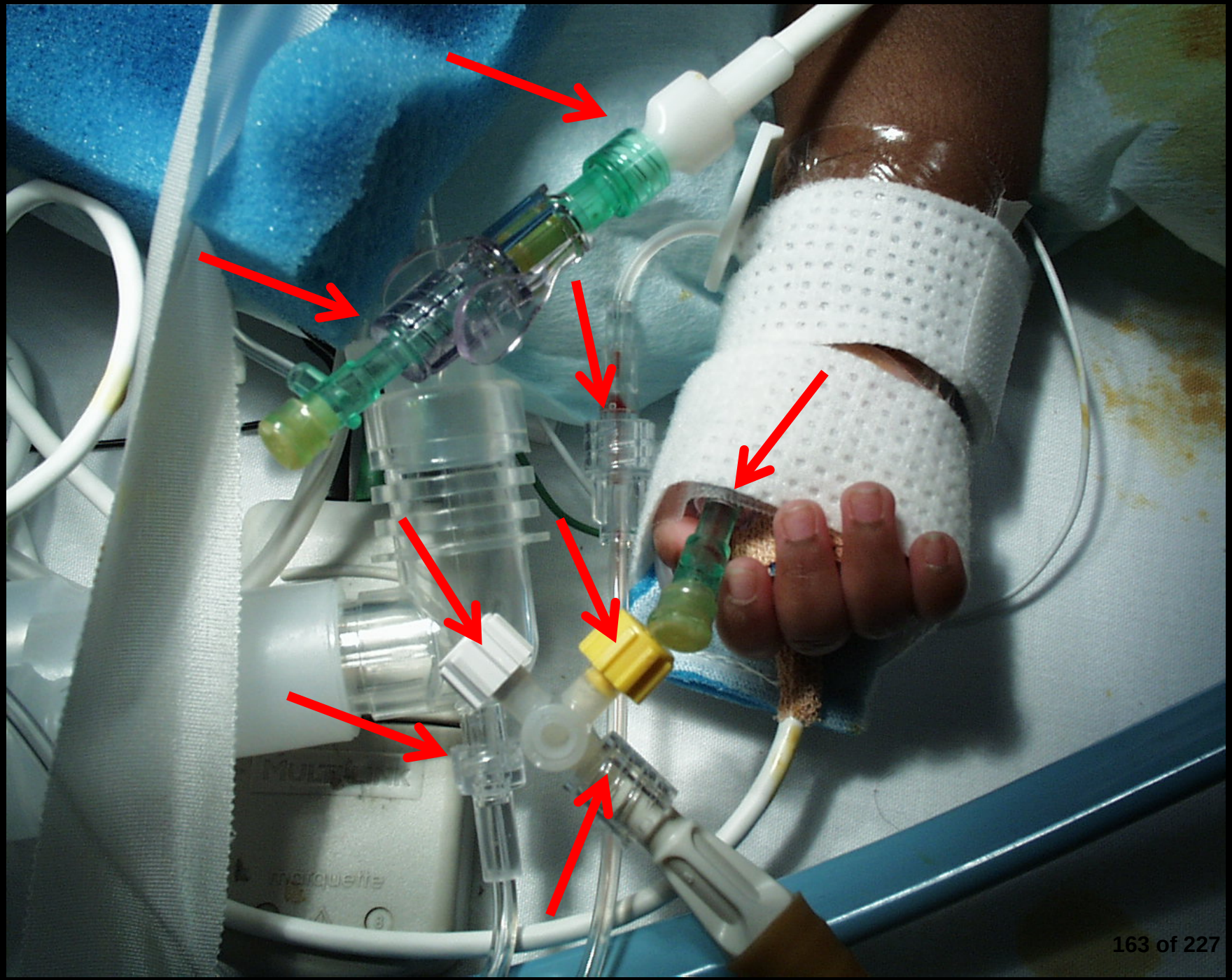
REASONS FOR AND SCOPE OF NEW CONNECTOR INITIATIVE

History of the problem

- Luer connectors were invented in the late 1890s to provide leak-free connections between glass hypodermic syringes and needles, while allowing easy fitting and removal by pushing together and pulling apart ("Luer slip"). Several years later, a variant was made with threads so that the connectors would be screwed together and secured ("Luer-lock"). Luer fittings became the standard for intravenous use, and then became popular for many other uses requiring small-bore connectors, from attaching blood pressure cuffs to inflation sources to connecting epidural catheters to anesthetic infusions.

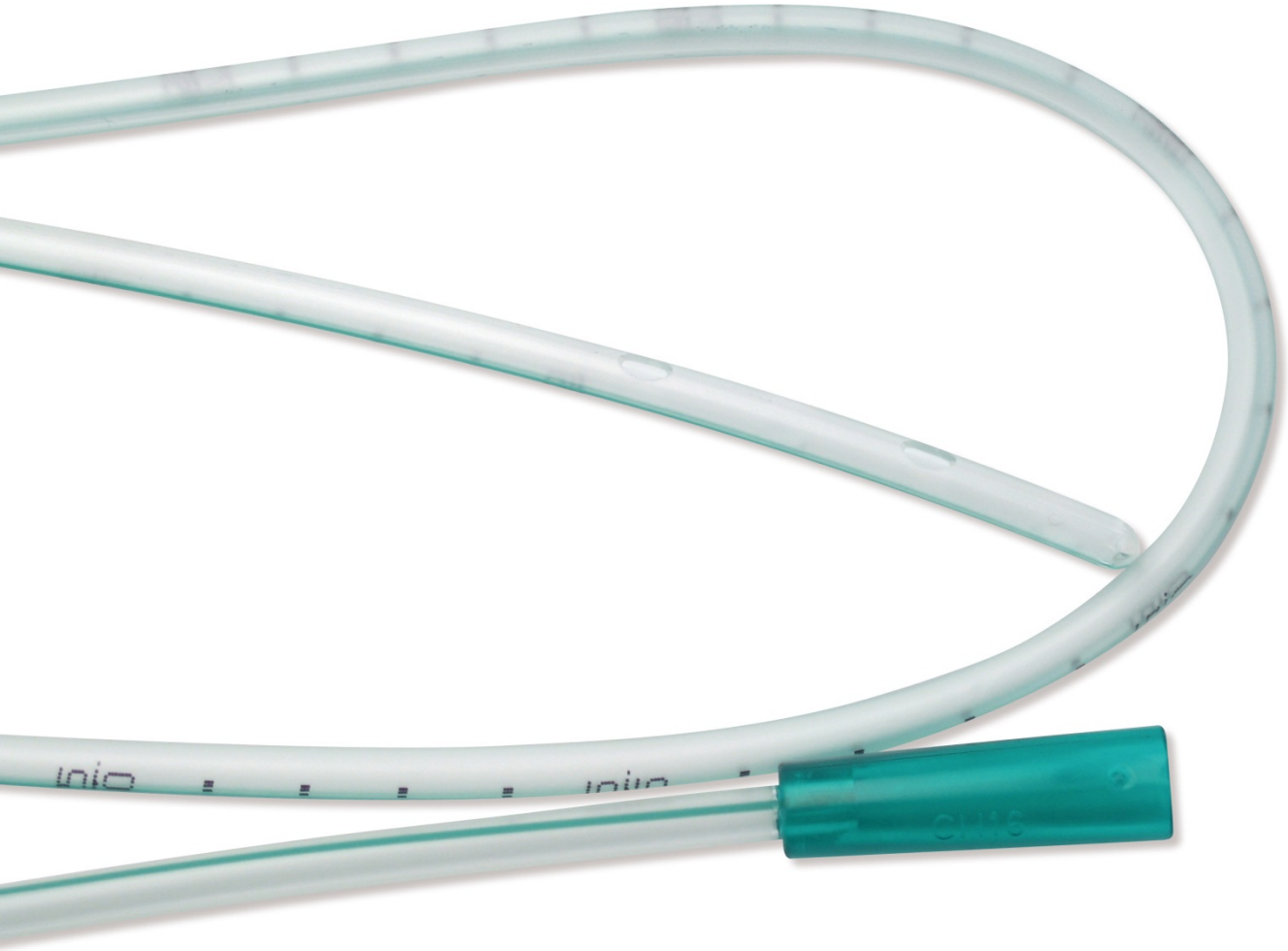
History (cont.)

- With so many different applications using the same connector, accidental cross-connections, some fatal, began to appear.
- Soon there will be international standards for specialized connectors specific to neuraxial (e.g., epidural and intrathecal), blood pressure cuff, enteral and breathing/ventilator systems; each mechanically protected from connecting with the other. These connectors will also be protected from connecting with Luer fittings, which will continue to be used for intravascular and hypodermic applications.
- The risk of deadly cross connections will be significantly reduced by adopting physically incompatible connectors for different uses.

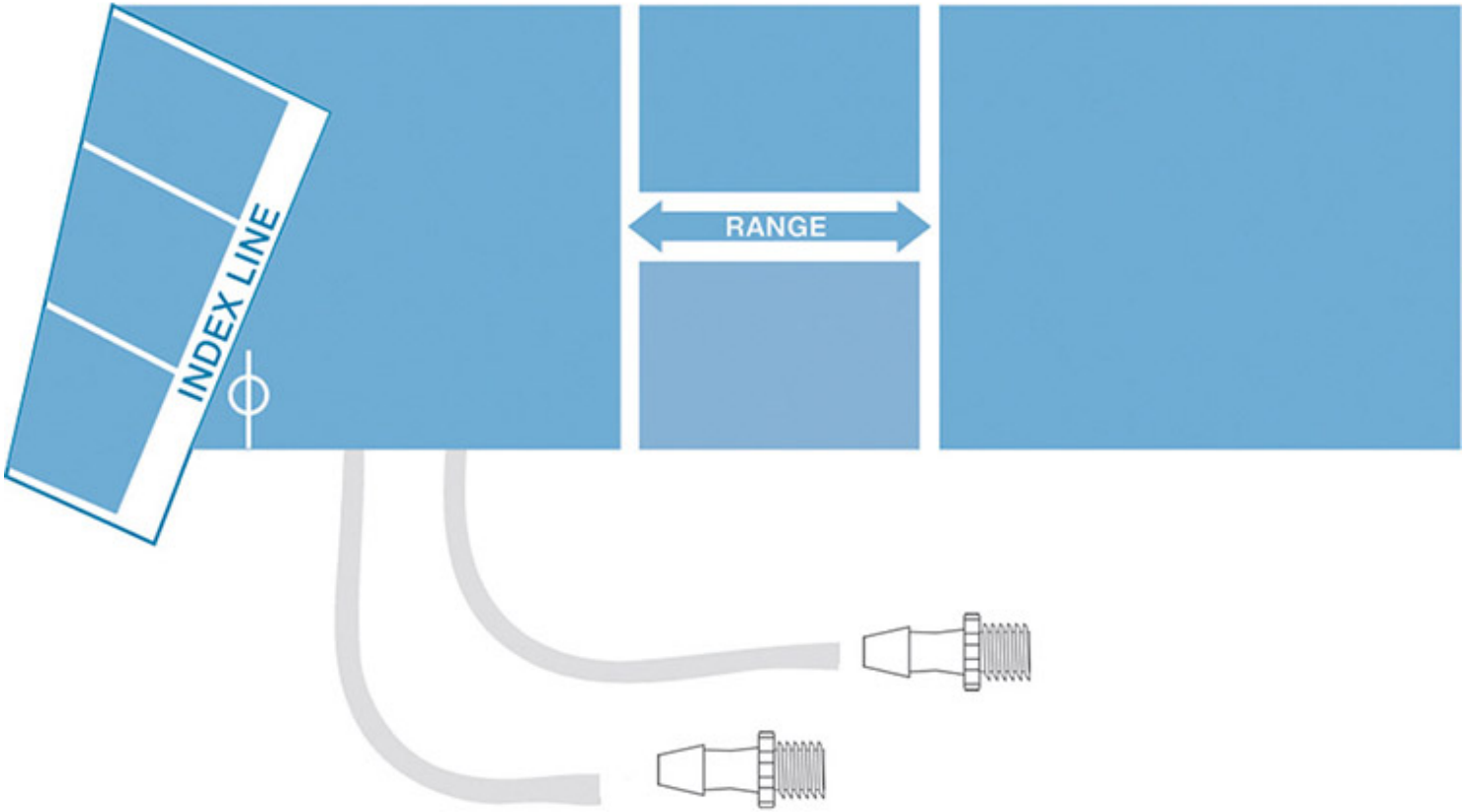


Breathing systems and driving gases

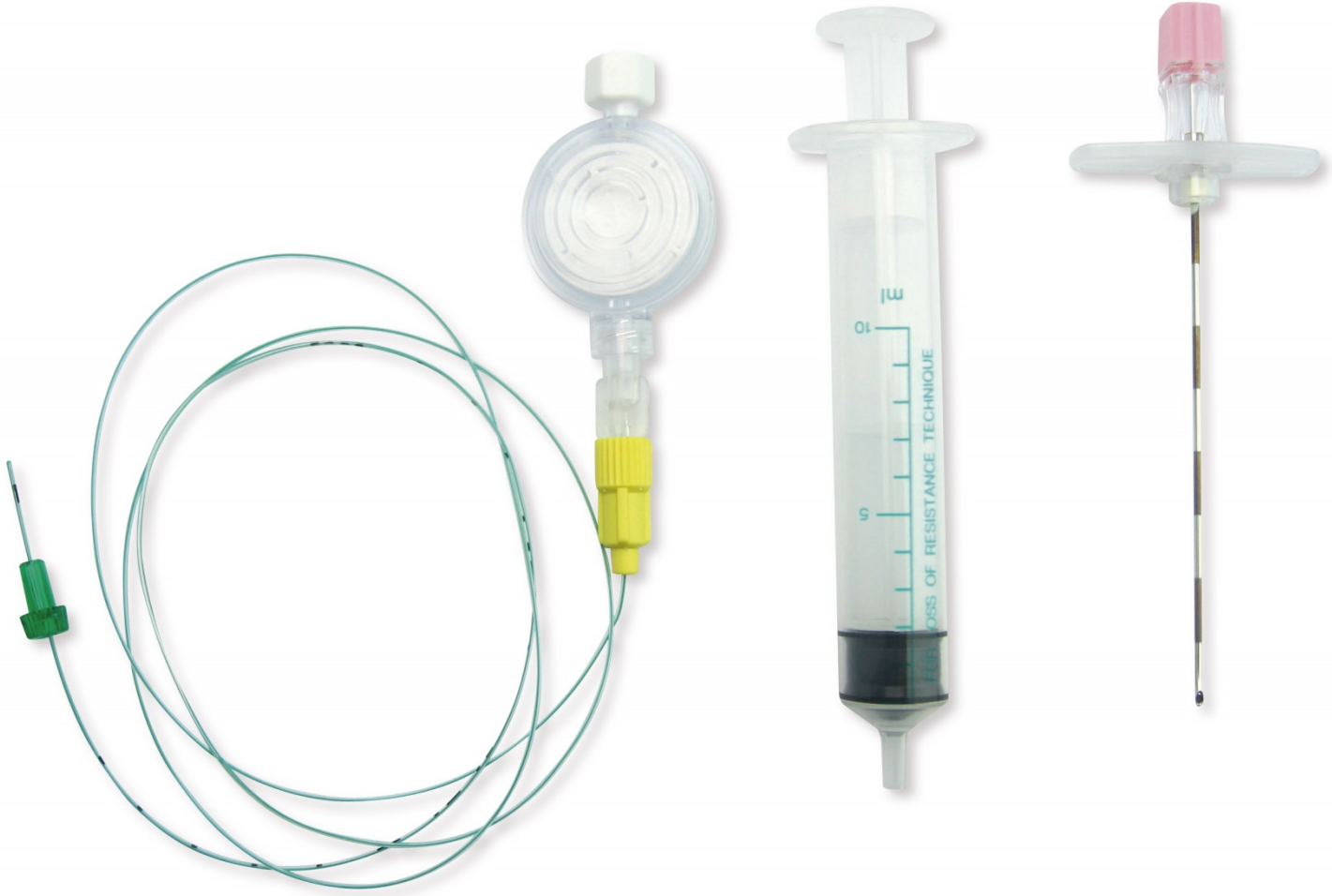
Enteral applications (not suction)



Limb cuff inflation



Neuraxial



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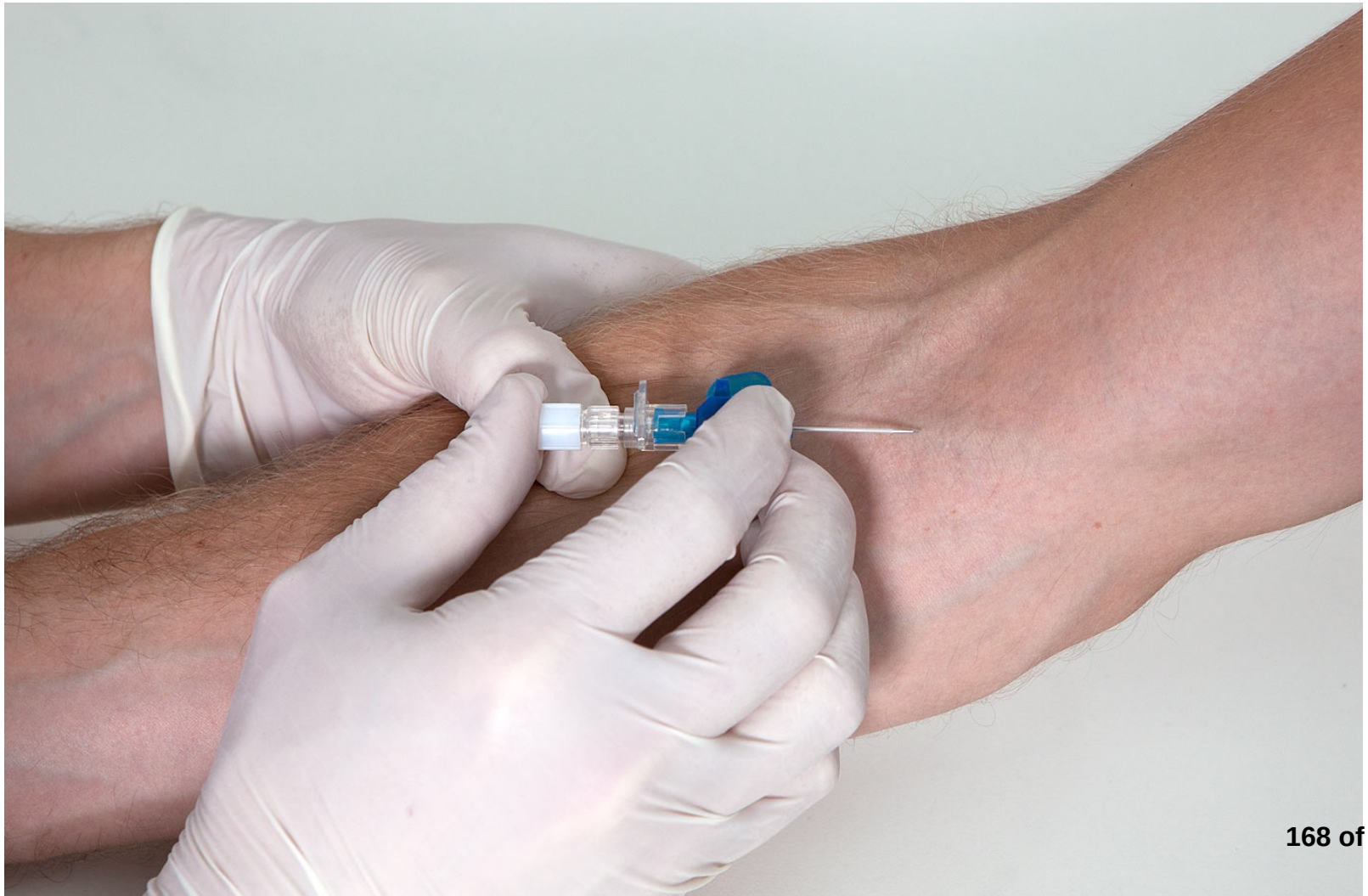
Intravascular/Hypodermic



WHY AN INTERNATIONAL STANDARDS INITIATIVE?

Proprietary standards have been tried

- **UK several years ago required non-compatible connectors for neuraxial use, but many problems arose**
- **Some styles of connectors caused usability issues during procedures**
- **Supply chain not standardized**
  - Some hospitals received distal connectors without proximal mates and didn't recognize the issue until a clinician could not successfully complete a procedure
  - Clinicians received surprises when new styles of connectors showed up
  - Patients transferred from one facility to another could face connection barriers if facilities using different proprietary connectors

More issues with proprietary connectors

- **Not completely sure that the misconnection problem is addressed – there will be a new testing procedure proprietary manufacturers may use to check for misconnections if they wish to, but:**
  - Won't crosscheck other proprietary connectors
  - As new standard connectors arrive, not clear whether proprietary connectors will be re-tested

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Scope of the international effort

Small bore connectors for liquids and gases in healthcare

- 80369-1: general requirements for small-bore connectors
- 80369-2: breathing systems and driving gases
- 80369-3: enteral
- *80369-4: urethral and urinary*
- 80369-5: limb cuff inflation
- 80369-6: neuraxial
- 80369-7: intravascular or hypodermic
- 80369-20: common test methods

Small bore connectors for reservoir delivery systems

- 18250-1: general requirements
- *18250-2: breathing systems and driving gases*
- 18250-3: enteral
- *18250-6: neuraxial*
- *18250-7: intravascular*
- 18250-8: citrate-based anticoagulant solution for apheresis
- *18250-9: irrigation*

Italic = under consideration, not in progress

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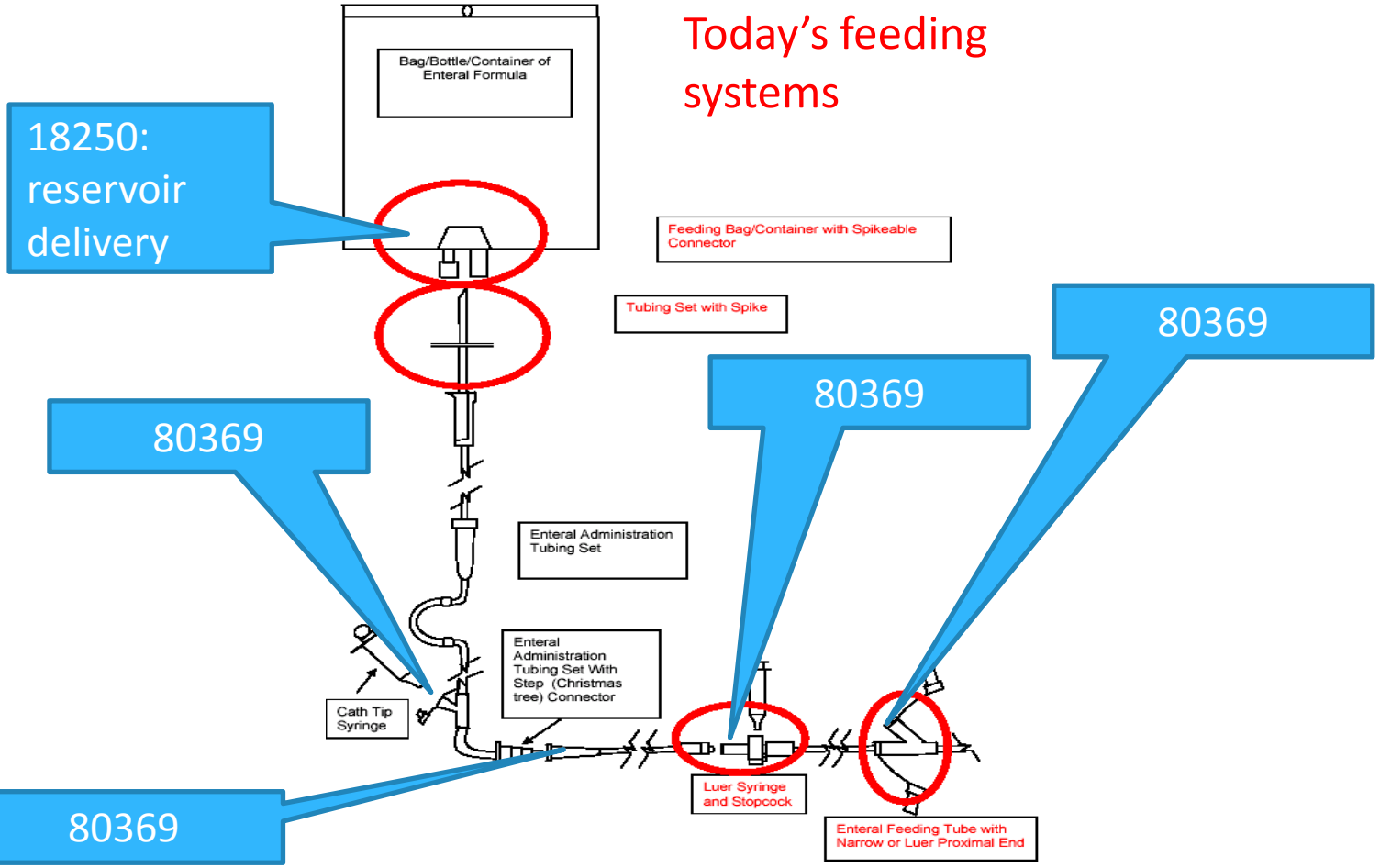
Two sets of standards (80369 and 18250)

Today's feeding systems



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The ISO standards process is multinational

- **31 countries, each with one vote**
- **Each country submits extensive comments and text revisions**
  - These are approved or not through consensus process
- **Several rounds of review and voting before standard is published**
- **Process is slow, and some countries have different view of urgency than others**
  - California deadline is major driver behind current ISO small bore connector standardization timeline

The ISO standards process is thorough

- **Extensive materials, manufacturing and usability testing**
- **New connectors should be about as usable as prior, with some improvements**
  - Fewer “Luer” leaks and glass syringe breakage—the Luer standard has been tightened
- **Enteral connector does not decrease medication dosing accuracy**
  - Tested

Color coding not in the standards

- Different manufacturers and different materials result in range of colors, even when standardized
- Color coding relies on memory and vision, not a forcing function
- Connectors might be color coded (e.g., purple for enteral), but this is not a standard requirement

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Colors used for other, conflicting purposes

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New designs to prevent cross-connections

Enteral

- **Reversed genders from IV**
  - Prevents enteral line attachment to patient's IV
- **Male distal, female proximal**
- **~ 20 % larger than IV connectors**
  - Prevents cross-connects

Neuraxial

- **About 20 % smaller than IV connectors**
  - Male IV connector too large for female neuraxial
- **Collar on all male connectors, not just lock connectors**
  - Male neuraxial collar interferes with larger female IV connector, prevents connection

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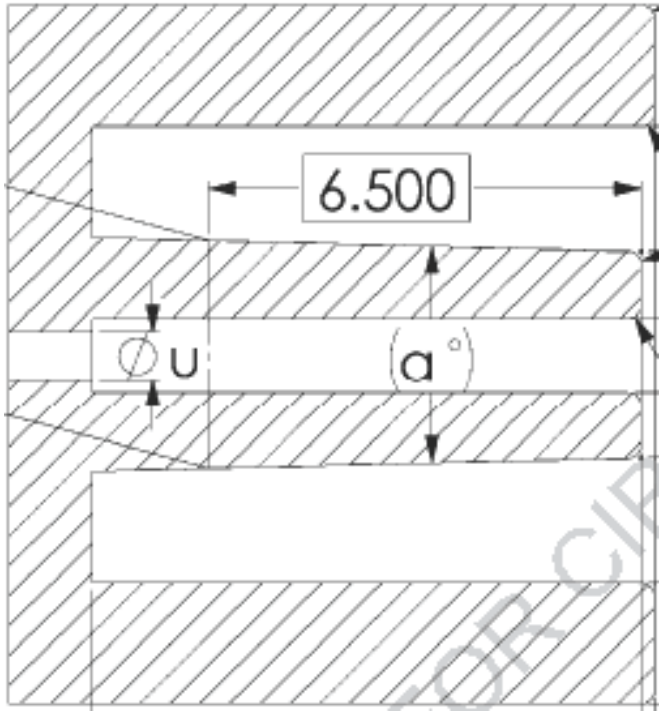
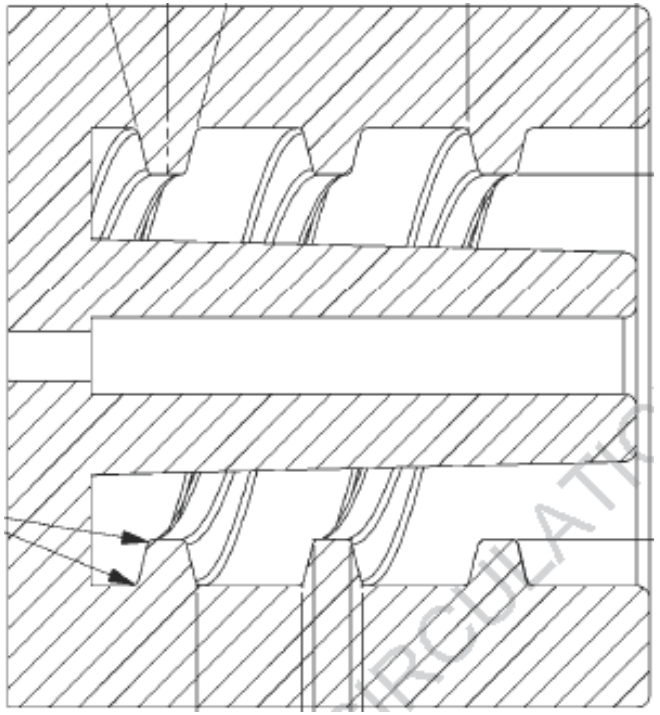
Traditional male “Luer slip” vs. “Luer lock”

Connector collar comparison

Neuraxial slip with collar



Neuraxial lock with collar



Neuraxial connector design

Reservoir connector

- Uses standard IV bag "spike"
- Does not prevent inadvertent use of IV tubing as an administration set

Patient access

- Prevents inadvertent connection of a neuraxial fluid line or neuraxial syringe to IV and vice-versa

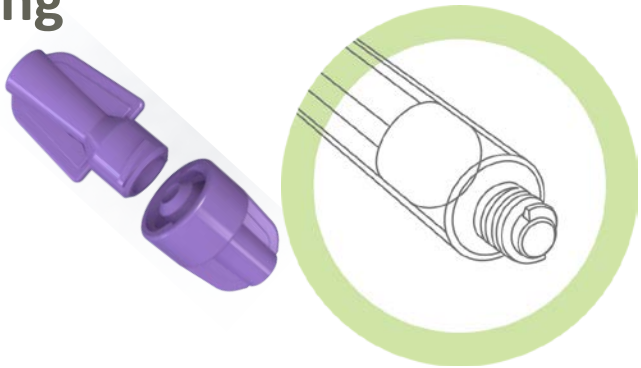
Enteral connector design

Reservoir connector

- Prevents inadvertent use of IV tubing as an administration set

Patient access

- Prevents inadvertent connection of enteral administration set to IV tubing



Usability testing example: enteral

- Participants were a mix of caregivers that work in an ICU or NICU, and CNAs or people with a close friend, family member, or themselves that requires enteral feeding and medication administration at home
- These three user groups represent a variety of environments where enteral feeding and medication administration is provided. ICU, n=20; NICU, n=20; home, n=24
- Participants also represent a mix of ages and genders

Usability testing example: enteral (cont.)

- **The objectives of the human factors study were to validate:**
  - Caregivers do not attempt to connect male/female connector from the enteral connector system to other ports coming out of the manikin's body.
  - Caregivers can successfully connect paired male/female enteral connector systems by twisting, or screwing, them into each other.
  - Caregivers can successfully administer enteral feeding or medication by having no leaks at the connection site due to participant error.

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STATUS REPORT AND TIMELINES

What does California require?

- **California law mandates:**
  - *Incompatible connectors* for unlike purposes (epidural vs enteral vs intravenous/hypodermic) by January 1, 2016
  - Applies to
    - General acute care hospitals
    - Acute psychiatric hospitals
    - Skilled nursing facilities
    - Special hospitals (dentistry or maternity)
- **California law does not mandate:**
  - Incompatible reservoir spikes
- **Most cases seem to be errors at connector level, but still need caution**

Neuraxial testing results

- Testing found that, under certain extreme circumstances, a male slip neuraxial connector could cross-connect to a female Luer connector with a big leak
- There were many ways it could be redesigned—the committee chose the version that could be tested the fastest, in view of California's deadline

Neuraxial timeline post-testing

- Testing failure resulted in six-month design freeze timeline slip
  - Did not delay overall ISO process
- Design now “frozen”

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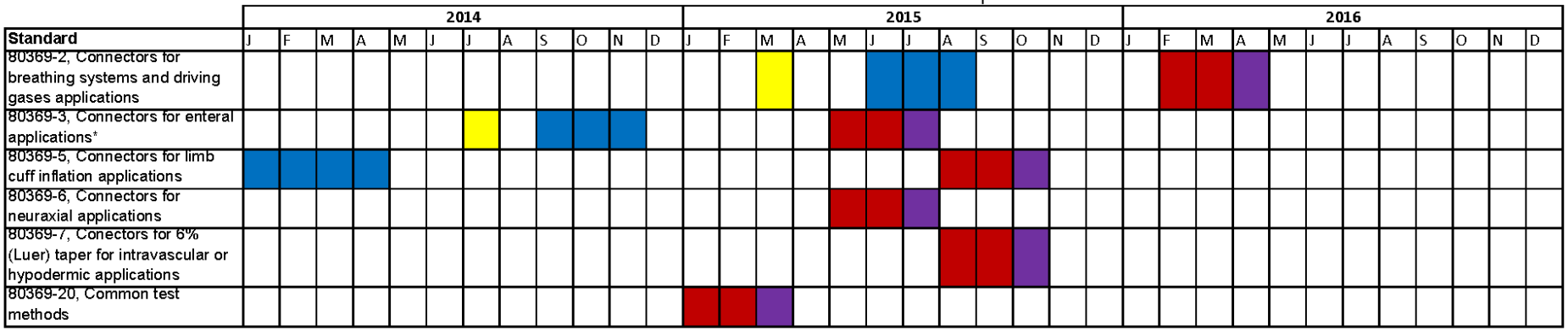
International standards timeline

80369 Small-Bore Connectors
International Standards Development Timeline



Key

Submission of DIS text to ISO	
DIS (Draft International Standard) balloting	
FDIS (Final Draft International Standard) balloting	
ISO publication	

*refers to second DIS

PLAN FOR INTRODUCTION OF NEW CONNECTORS

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Enteral timeline (USA)

- 2015 late Q1/early Q2: Customers currently ordering sets with the stepped/Christmas tree connector will receive transition feeding/administration sets. These sets are compatible with both current feeding tube connections and new ISO 80369-3 standard connector.
- 2015 Q2: Flush and bolus feed syringes with the connector will be available (proximal 80369-3 connector)
- 2015 Q3: New enteral feeding tubes with ISO standard connector will be available (distal 80369-3 connector)
- 2016: Current universal connector no longer available, transition connectors no longer needed except for old feeding tubes

Neuraxial timeline (USA)

- **Active discussions and planning ongoing**
- **Unlikely that product will meet California deadline**
  - Contemplating July 2016 general availability
- **Unlike enteral connectors, expect proximal and distal connectors at same time**
  - Lines tend not to stay in patient between care settings
  - Will not include transition connectors

AB 444

- **Delays deadline for epidural connectors**
  - From 1/1/2016 to 1/1/2017
- **As with earlier delays, this delay intended to allow orderly roll-out of ISO standard connectors**
  - While legislation allows proprietary connectors that are already available, intent is to use ISO standard

Why does it take so long?

- **Requires new, expensive tooling**
  - Most vendors reluctant to start "cutting steel" until standard frozen
  - Sampling, QA needed
  - Typically one year design to production
- **For neuraxial connectors, complicated coordination of suppliers to produce parts for kits**
- **FDA streamlining process**
  - No need for new 510k if only change is ISO connector

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Information sources for roll out plans

- **California Hospital Association, Hospital Quality Institute, California Hospital Patient Safety Organization**
  - Working directly with the manufacturers and ISO standards committees
  - One of few clinician representatives active in this phase of adoption
  - www.chpso.org/post/new-connectors-are-coming
- **Enteral connectors: "Stay Connected 2014" www.stayconnected2014.org**
  - Sign up for mailing list at eepurl.com/K3hCP
  - CHPSO is working to facilitate a similar collaboration for neuraxial connectors
- **Association for the Advancement of Medical Instrumentation (AAMI)**
  - CHPSO is a member
  - www.aami.org/hottopics/connectors/

RISKS, NEW AND OLD, WITH THE TRANSITION AND NEW CONNECTORS

During changeover: Inconsistent adoption of enteral connectors

- **Some facilities may adopt the new devices before others**
- **If patient with new feeding tube is transferred to facility with old devices, that facility cannot use the tube**
  - Thus the staged rollout, with six months before tubes start being used
- **If patient with an old device is transferred to facility with new devices, transition connector is needed**
- **Care delays unless recipient facility has connector**
- **Recommendations:**
  - Assess connector types on transfer and on admission to anticipate and resolve connector challenges
  - Ensure that facility is fully stocked with new feeding/administration sets (with transition connectors) *before* the new feeding tubes hit the market: before 3Q 2015

Proximal spike for neuraxial uses

- **No change in proximal spike, so both neuraxial and intravenous administration sets can attach to neuraxial and intravenous solution reservoirs**
- **Supplying an intravenous administration set with a neuraxial solution will "force" intravenous administration unless caregiver double checks**
- **Accidentally mixing intravenous and neuraxial sets in a bin could lead to wrong route errors**
- **Recommendations:**
  - Manufacturers plan to prominently distinguish connectors on the label, details not finalized
  - Pharmacy can package neuraxial fluid reservoirs with neuraxial sets (e.g., rubber band together)
  - Consider whether stocking neuraxial sets on wards is wise or not (e.g., risk of mix-ups in bins)

Mis-filled syringes or fluid reservoirs

- Remain an issue, currently appears to happen much less frequently than misconnections of properly filled containers
- Nurses still need to be aware of correct route for each medication, and systems (e.g., CPOE) should continue to check for proper route
- **The new connectors are a component of "defense in depth" for potentially disastrous events, not a substitute for current defenses**

Cross-connections with male slip

- Limited "space" to design interferences between all the small-bore connectors.
- Lack of threads in slip connector (and collar in Luer slip) removes some potential interferences
- Cross-connections that do occur appear to be low risk
  - Primarily interruption of IV therapy, not injection of harmful substances into wrong route
- **Recommend minimizing use and storage of Luer slip devices**

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HOSPITAL MATERIAL MANAGEMENT CHALLENGES

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Purchasers' influence

- **January 2016 deadline strictly applies only to California**
- **USA probably will proceed at same pace unless supply is tight**
  - Supply may be tight for epidural connectors initially
- **To ensure compliance with the law, hospitals should identify, as soon as possible, suppliers that should meet the deadline**
  - Create market demand in advance of changeover, incentivize suppliers that move quickly to meet California legal requirements
  - GPOs have prominent role in USA supply chain and should be partner in this effort
  - This may mean delaying adoption (by several months) in other states
  - This also may mean that GPOs and hospitals will need to switch suppliers if the traditional suppliers might fail to meet the required deadline

Material management changes

- **More SKUs**
  - Syringes in at least three fitting types, multiple types for needles, etc.
  - Infusion pump tubing in multiple types
  - Connectors, other tubing, etc.
- **Need to identify where neuraxial and enteral uses occur**
  - In past, didn't necessarily need different types of fittings on the wards, now will
- **Stock "transition connectors" during the transition period**
  - Enables cross fit conic-ended enteral tubes to new fitting

- **Recommend facility-wide rollout rather than ward by ward**
  - Supply chain will be rapidly emptied of old-style connectors for use-specific devices (e.g., spinal needles, feeding tubes)
  - Differently phased rollouts will confuse and frustrate clinicians who work in multiple locations
  - Will roll out proximal and distal sets separately for enteral uses, using bridge connectors in the transition
  - Neuraxial devices tend to stay in patients for less time, roll out proximal and distal sets simultaneously

Potential material management surprises: neuraxial

- **Intravenous/hypodermic supplies may currently be used for neuraxial uses without the knowledge of materials management**
  - Major nerve blocks, while not technically “neuraxial”, will be included
  - Common needles (e.g., 22g long) may be needed in both Luer and neuraxial fittings
  - IV catheters may also be used for major nerve blocks
- **May be asked to supply neuraxial connectors for chemical nerve ablation use, such as in a pain clinic**
- **Pharmacy, clinician-users, and materials management need to coordinate plans**

Other potential neuraxial material management surprises

- **Spinal needles may be used for non-neuraxial purposes**
  - E.g., amniocentesis, joint space aspiration
  - These uses will also need to be converted to the new connectors
- **California law only requires the new connector for epidural uses**
  - Some manufacturers, strapped for time, may delay production of the new spinal needles
- **Inventory neuraxial uses and supply needs through questionnaire: sample survey will be sent to webinar participants**
  - At a minimum, include oncologists, anesthesiologists, pain specialists, interventional radiologists, and ED physicians in the survey

Potential material management surprises: enteral

- **Medication administration may be carried out in different ways**
  - Work with pharmacy to identify medication uses
- **Many of the enteral lines the hospital deals with were introduced into the patient elsewhere**
  - Patients will come in to hospital with a variety of connector types for their indwelling enteral lines
  - Work with GI, nursing, to identify current connector use, current workarounds for odd connectors, etc., then find ways to address these issues with the new connector sets
  - Patients changing feeding tubes at home may use cut-off Foley catheters to save money, and thus may still have conic connectors even after new feeding tubes are on the market

Other recommendations

- Prepare by assessing systems processes and protocols that may need to change
- Work with suppliers to coordinate transition plans
- Plan to train clinicians and materials management staff for impending changes
- Be aware that one neuraxial use still not covered by connector plans: epidural blood patch, an uncommon procedure requiring both intravenous and neuraxial access
  - May need to “cobble together” items to have a useful procedure kit
  - Probably will get guidance from Anesthesiology societies

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Stay tuned for more

- CHPSO continues to work to address these issues
- Subscribe to CHPSO newsletter (eepurl.com/od9Qj), CHA daily news
- Contact Rory Jaffe (rjaffe@chpso.org) with any questions

Questions

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High price of specialty drugs prompts backlash

BY HUDSON SANGREE - HSANGREE@SACBEE.COM

04/04/2015 11:00 AM | Updated: 04/05/2015 9:59 AM

For hepatitis C patients, new drugs introduced in the past two years offer a cure that's miraculous when compared with former treatments for the potentially fatal virus.

Instead of taking a long course of drugs with miserable side effects, patients can be cured in a matter of weeks. The drugs could change the lives of millions of people – at a price.

One of the drugs, Sovaldi, cost $1,000 a pill when it went on the market in the United States in late 2013. Another drug called Harvoni, made by the same manufacturer, had a list price of $1,125 per pill when it debuted last fall. A typical 12-week course of treatment with Harvoni would cost $94,500 at that price.

The cost of these new hepatitis drugs has inflamed debate about whether pharmaceutical companies are charging outlandish amounts to treat life-threatening diseases and has prompted legislative efforts this year to rein in drug costs.

"It was sort of a spark on a pile of dynamite," said Emalie Huriaux, director of state and federal affairs for Project Inform, a San Francisco-based group that advocates for patients with hepatitis C and HIV/AIDS.

Medical advances are expected to produce a series of blockbuster drugs in the coming years to treat cancer, Alzheimer's disease and other severe and commonplace afflictions. Patient advocates worry that drugmakers will charge sky-high prices for each new drug while their patents exclude competitors.

"It's not just Sovaldi. It's all the ones that come after," said Anthony Wright, executive director of the patient advocacy group Health Access California. "Sovaldi set a new price point for the next wave of drugs."

An unusual coalition of patient advocates and health plans, groups often at odds, are calling for greater transparency in drug pricing. They want to know why the drugs cost so much in the United States when in other parts of the world – including Europe, Canada and Egypt – Sovaldi and Harvoni are sold for a fraction of the price.

"We feel like there hasn't been a lot of explanation why drugs are priced at this rate," said Nicole Kasabian Evans, vice president for communications at the California Association of Health Plans. "There are about 12 blockbuster drugs set to launch this year, and we think it's important to peel back the onion and get a better understanding of why drugs are priced this way."

Medicines to treat rare conditions, called "orphan drugs," for years have been priced high to recoup the expense of developing a drug for a relatively small number of patients. But until Sovaldi, it was unheard of for a drug aimed at a commonplace disease to cost so much, critics said.

The U.S. Centers for Disease Control and Prevention estimates that 3.2 million people in the United States have a chronic hepatitis C infection that can lead to cirrhosis or liver cancer. The World Health Organization estimates there are 130 million to 150 million people worldwide with chronic hepatitis C, and that 350,000 to 500,000 people die from liver damage and related conditions each year.

Multiply the price of the new hepatitis C drugs by the number of potential patients, and you get an idea of the costs to patients, health insurers and government programs such as Medi-Cal. The issue would be compounded if other new drugs are priced similarly.

The investigative news organization ProPublica recently reported that the federal Medicare program spent $4.5 billion last year on new treatments for hepatitis, including $3 billion on Sovaldi and $670 million on Harvoni. That was 15 times more than Medicare spent the year before on older treatments for hepatitis C, according to the report.

In California, Gov. Jerry Brown added $300 million to his proposed budget for the coming fiscal year to cover additional costs of new hepatitis C treatments and created a task force to examine the impact of high-cost specialty drugs.

Quick cure, high price

Sovaldi and Harvoni are made by Gilead Sciences, a company headquartered south of San Francisco in Foster City. In February, Gilead reported that its global "hepatitis C revenue" totaled $3.8 billion for the last three months of 2014. In an earnings conference call, Gilead Executive Vice President Paul Carter said $3.2 billion of that revenue came from the United States.

"To date, approximately 140,000 patients have started (hepatitis C) therapy on a Gilead product in the United States," Carter said.

Gilead spokeswoman Cara Miller declined an interview request. In an emailed statement, she said the drugs' prices are justified by their effectiveness in curing hepatitis C, reducing future treatment costs.

"Unlike long-term or indefinite treatments for other chronic diseases, Sovaldi and Harvoni offer a cure with as little as eight weeks of treatment for many patients taking Harvoni," the statement said. "We believe the price of Sovaldi and Harvoni reflect the value of these medicines."

The company has been under pressure to lower prices. In December, the U.S. Food and Drug Administration approved a competitor's drug that has proven effective at curing hepatitis C and also came with a price tag of about $1,000 a pill.

Gilead has been negotiating lower prices with government programs and private health insurers. In February, the company told investors it expected to provide average discounts of 46 percent on Harvoni and Sovaldi in 2015.

"We are working to enable access to our (hepatitis C) treatments for as many patients as possible, and we continue to work with public and private payers to facilitate broad patient access in the context of a competitive marketplace," Miller said in the statement.

Gilead also offers treatment at little or no cost to uninsured or underinsured patients through its Support Path program.

Tammy Lovelace of Sacramento said she tried for a year with the help of her health care provider to get Sovaldi or Harvoni through her insurance company but was denied repeatedly. Recently, Gilead gave her Harvoni for free through its Support Path program, she said.

Lovelace just started taking Harvoni and hopes to be cured of hepatitis C in a few months. She said the disease makes her feel sick and lethargic, and she sometimes sleeps up to 20 hours a day.

Lovelace said she was infected as an intravenous heroin user but has been clean for three years. Though grateful for the possibility of a cure, she said she found it hard to understand the immense price of the drugs.

"Who in their right mind would be an intravenous drug user and have $80,000?" she said. "I just want a better quality of life. I didn't get clean to die of hep C."

Demands for disclosure

Both the California Association of Health Plans and Health Access California are backing a bill introduced this year by Assemblyman David Chiu, D-San Francisco, that would require drugmakers to disclose the costs and profits of any drug or course of treatment that costs more than $10,000 per year. Assembly Bill 463 is awaiting a hearing by the lower house's Health Committee.

"The industry has told us the highest drug prices are driven by costs," Chiu said. "If that's the case, then we're simply asking for information to help policymakers understand."

Another bill by Assemblyman Rich Gordon, D-Menlo Park, addresses the issue of how the costs of expensive treatments are split between patients and health plans. Some plans placed all treatments for HIV and hepatitis C into a category that requires patients to pay up to 20 percent of the drug's cost rather than a copay of $10 or $20.

Patients can quickly shell out thousands of dollars before insurance starts to cover a drug's full cost. Some say the cost sharing discriminates against those with conditions such as hepatitis C, HIV/AIDS and multiple sclerosis by charging more for life-saving treatments.

Insurance companies used to deny coverage or charge high premiums to patients with chronic conditions that were pricey to treat. The federal Affordable Care Act prohibited health plans from discriminating against enrollees with pre-existing conditions.

"There is evidence, however, that insurers are resorting to other tactics to dissuade high-cost patients from enrolling," researchers Douglas Jacobs and Benjamin Sommers, with the Harvard School of Public Health, wrote in an article published in the New England Journal of Medicine in January.

Earlier this year, Kaiser Permanente reversed its decision to place many HIV drugs in its highest-cost tier of specialty medications. Other health plans persist in the practice.

Gordon's AB 339 would require health plans to cover medically necessary drugs and to limit cost sharing so that patients wouldn't be deterred from seeking treatment.

"Our goal with AB 339 is to promote access to essential lifesaving medications for Californians who need them," Gordon said in a news release. "Cost should not be an obstacle."

Health Access California sponsored the legislation, but the California Association of Health Plans is not supporting it because it would transfer costs from patients back to insurers. The bill is scheduled to be heard by the Assembly Health Committee on April 28.

"We're giving a false sense to consumers that we're lowering drug costs when in reality we're just shifting costs," said Kasabian Evans, of the California Association of Health Plans. "We need to have a bigger discussion of how we can ensure health care remains affordable."

Call The Bee's Hudson Sangree, (916) 321-1191.

Comments (1) (#tabs-b0710947-1-tabPane-2)

Bill No.	Title/Description	Current Legislative Status	Notes / Dates
1. CA AB 26 **Jones-Sawyer**	**Medical Cannabis** Enacts the Medical Cannabis Regulation and Control Act. Creates a related division within the Department of Alcoholic Beverage Control to register persons for the cultivation, manufacture, testing, transportation, storage, distribution, and sale of medical cannabis with the State. Relates to the taxation of such product. Creates a related fund. Requires the implementation of related regulations. Requires specified record keeping. Provides the conditions and procedures for recommending marijuana to patients. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	To ASSEMBLY Committee on HEALTH 1/22/15 To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and HEALTH 3/9/15	
CA AB 34 **Bonta**	**Medical Cannabis: State Regulation** Declares the intent of the Legislature to enact legislation that would establish a comprehensive and uniform state regulatory structure to govern the cultivation, processing, testing, and distribution of medical cannabis. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 12/01/2014 03/26/2015 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS. 3/26/2015 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments 03/26/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS 3/26/15.	
CA AB 73 **Waldron**	**Medi-Cal: Benefits: Prescription Drugs** Declares the intent of the Legislature to enact legislation to include specified therapeutic drug classes, as prescribed by a licensed prescriber in his or her reasonable, professional judgment, as a covered Medi-Cal benefit, to the extent permitted by federal law. ISSUES: AK*, AO, BJ LOBBYIST: BG*, TRT POSITION: F	Introduced 12/18/14 To ASSEMBLY Committee on HEALTH 3/12/15 From ASSEMBLY Committee on HEALTH with author's amendments 3/16/15 In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH 3/16/15	

3. CA AB 159 **Calderon**	**nvestigational Drugs, Products, and Devices** Permits a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with terminal illnesses. Authorizes a health benefit plan to provide coverage for such products made available pursuant to these provisions. Prohibits disciplinary action for any product or drug recommendation if consistent with standards of care. Prohibits altering a provider's Medicare of Medicaid participation due to any access recommendation. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F, X	To ASSEMBLY Committees on HEALTH and BUSINESS AND PROFESSIONS 2/2/15	
7. CA AB 266 **Cooley**	**Medical Marijuana** Establishes a Bureau of Medical Marijuana Regulation. Requires the bureau to license and regulate dispensing facilities, cultivation sites, transporters, and manufacturers of medical marijuana and medical marijuana products, subject to legal ordinances. Requires a background check of applicants for licensure to be administered by the Department of Justice, and submission of a statement signed by an applicant, under penalty of perjury, that the information on his or her application is true. ISSUES: BJ, DP* LOBBYIST: TRT POSITION: F, X	Assembly - Referral Pending 3/2/15 To ASSEMBLY Committees on BUSINESS AND PROFESSIONS and LABOR AND EMPLOYMENT. 3/9/15	
10. CA AB 339 **Gordon**	**Health Care Coverage: Outpatient Prescription Drugs** Requires health care service plan contracts and policies of health insurance provide coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs that do not have a therapeutic equivalent. Requires copayments, coinsurance, and other cost sharing for these drugs to be reasonable. Requires those contracts and policies to cover single-tablet and extended release prescription drug regimens. ISSUES: BJ, DG, DP* LOBBYIST: TRT POSITION: F	To ASSEMBLY Committee on Health 2/23/15	

11. CA AB 374 **Nazarian**	**Health Care Coverage: Prescription Drugs** Prohibits a health care service plan or health insurer that provides medication pursuant to a step therapy or first-fail requirement from applying that requirement to a patient if, in the professional judgment of the prescribing physician, the step therapy or first-fail requirement would be medically inappropriate for that patient. ISSUES: BJ*, DG, DP LOBBYIST: TRT POSITION: F	Introduced 2/17/15 To ASSEMBLY Committee on HEALTH. 3/2/15 From ASSEMBLY Committee on HEALTH with author's amendments. 03/02/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH. 3/2/15	
14. CA AB 463 **Chiu**	**Pharmaceutical Cost Transparency Act of 2015** Requires each manufacturer of a prescription drug that has a specified wholesale acquisition cost to file a report on the costs for each qualifying drug to the Office of Statewide Health Planning and Development. Requires the Office to issue a report to the Legislature outlining the information in the manufacturer's report and to post the report on its Internet Web site. Requires the Office to convene an advisory workgroup to develop a form for such reporting requirements. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/23/15 To ASSEMBLY Committee on HEALTH 3/5/15	
15. CA AB 486 **Bonilla**	**Centralized Hospital Packaging Pharmacies: Labels** Requires certain information be displayed on a human-readable unit-dose label, and that information to be retrievable by the pharmacist using the medication lot number or control number. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/23/15 To ASSEMBLY Committees on HEALTH and BUSINESS AND PROFESSIONS 3/5/15	
24. CA AB 611 **Dahle**	**Controlled Substances: Prescriptions: Reporting** Authorizes an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the Controlled Substance Utilization Review and Evaluation System Prescription Drug Monitoring Program regarding the controlled substance history of an applicant or a licensee under the Department of Consumer Affairs, for the purpose of investigating the alleged substance abuse of a licensee. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F, X	Introduced 2/24/15 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS 3/9/15 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.03/24/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.3/24/15	

26. CA AB 623 **Wood**	**Prescription Drugs** Makes technical nonsubstantive changes to the Knox-Keene Health Care Service Plan Act of 1975. States the intent of the Legislature to enact legislation to address the problem of prescription opioid pain reliever abuse and would make related findings and declarations. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/24/15 To ASSEMBLY Committees on HEALTH and BUSINESS AND PROFESSIONS. 03/26/2015 From ASSEMBLY Committee on HEALTH with author's amendments. 03/26/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.3/26/15	
27. CA AB 627 **Gomez**	**Audits of Pharmacy Benefits** Makes nonsubstantive changes to existing law that imposes specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan and provides that those requirements do not apply to an audit conducted because a pharmacy benefit manager, carrier, health benefit plan sponsor, or other 3rd-party payer has indications that support a reasonable suspicion that criminal wrongdoing, willful misrepresentation has occurred. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/24/15 To ASSEMBLY Committees on HEALTH and BUSINESS AND PROFESSIONS.03/26/2015 From ASSEMBLY Committee on HEALTH with author's amendments.03/26/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.3/26/15	
29. CA AB 684 **Bonilla**	**Pharmacy** Relates to the Pharmacy Law. Relates to passage of the North American Pharmacist Licensure Examination. Requires the board to report that pass rate information to the appropriate policy committees of the Legislature and the Department of Consumer Affairs. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/24/15 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS 3/9/15	
32. CA AB 788 **Chu**	**Pharmacy** Makes nonsubstantive changes to the Pharmacy Law that requires an oral or an electronic data transmission prescription to be reduced to writing by the pharmacist and to be filled by, or under the direction of, the pharmacist. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/25/15 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS 3/26/15 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.03/26/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.3/26/15	

37. CA AB 1069 **Gordon**	**Prescription Drugs: Collection and Distribution** Makes a technical, nonsubstantive change to existing law that authorizes a county to establish a repository and distribution program under which a pharmacy may distribute surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies and prohibits the donation of controlled substances to the repository and distribution program, and prohibits the sale of any medication that does not meet the donation criteria. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/26/15	
38. CA AB 1073 **Ting**	**Pharmacy Law** Amends the Pharmacy Law that requires the Board of Pharmacy to promulgate regulations that require a standardized, patient centered, prescription drug label on all prescription medicine dispensed to patients. Removes an obsolete date. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/27/15 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS 3/19/15 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments. 04/06/2015 In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS. 04/06/2015	
43. CA AB 1359 **Nazarian**	**Optometry Therapeutic Pharmaceutical Agents** Changes all references to a certificate to use therapeutic pharmaceutical agents to refer to a therapeutic pharmaceutical agents certification. Deletes certain requirements for an applicant for a therapeutic pharmaceutical agents certification who graduated from a State accredited school of optometry, and is licensed as an optometrist in the State completing a certain didactic course. Requires the applicant to complete a preceptorship and education in ocular and systemic diseases. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/27/15 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS. 3/23/15	
44. CA AB 1394 **Thurmond**	**Prescription Drugs** Relates to California Discount Prescription Drug Program, administered by the State Department of Health Care Services, under which qualified individuals are provided with prescription drugs at reduced prices that result from rebate agreements between the department and drug manufacturers. Makes a technical, nonsubstantive change to a provision related to the program. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/27/15	

47. CA SB 149 **Stone**	**Investigational Drugs: Biological Products or Devices** Permits a manufacturer of an Investigational drug, biological product, or device to make the product available to eligible patients with terminal illnesses. Provides that the act does not require a health benefit plan or governmental agency to provide coverage for the cost of any investigational drug, biological product, or device made available pursuant to these provisions. Authorizes a health benefit plan to provide coverage for an investigational drug, biological product of device. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F, X	To SENATE Committees on HEALTH and BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT 2/19/15	
49. CA SB 202 **Hernandez**	**Controlled Substances** States the intent of the Legislature to enact legislation relating to the deceptive packaging and marketing of synthetic drugs. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	To SENATE Committee on RULES 2/19/15 Re-referred to SENATE Committee on JUDICIARY 3/18/15	
50. CA SB 282 **Hernandez**	**Health Care Coverage: Prescription Drugs** Authorizes the prescribing provider to additionally use an electronic process developed specifically for transmitting prior authorization information that is consistent with the standardized form and that meets the National Council for Prescription Drug Programs' SCRIPT electronic prior authorization standards. ISSUES: BJ*, DG, DP LOBBYIST: TRT POSITION: F	Introduced 2/19/15 To SENATE Committee on HEALTH 3/5/15	
55. CA SB 423 **Bates**	**Pharmaceutical Waste: Over-the-Counter Drugs** Excludes from the definition of pharmaceutical waste, for purposes of regulation under Medical Waste Management Act, any over-the-counter human or veterinary drug or dietary supplement that is, among other things, characterized and managed as a hazardous or solid waste and, with respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state. ISSUES: BJ, CLH*, DP LOBBYIST: KAS*, TRT POSITION: F	Introduced 2/25/15 To SENATE Committee on ENVIRONMENTAL QUALITY 3/5/15	

56. CA SB 447 **Allen**	**Medi-Cal: Clinics: Drugs and Supplies** Revises a specified reimbursement formula under the Medi-Cal program. Requires the clinic dispensing fee to be the difference between the actual acquisition cost of a drug or supply, to be calculated not less than annually, and the Medi-Cal reimbursement rate. Removes the cap on reimbursement that is based on the net cost of drugs or supplies when provided by retail pharmacies under the Medi-Cal program. ISSUES: AK*, AO, BJ, DP LOBBYIST: BG*, TRT POSITION: F	Introduced 2/25/15 To SENATE Committee on HEALTH 3/5/15	
58. CA SB 482 **Lara**	**Controlled Substances: Reporting** Specifies that the dispensing pharmacies and clinics are required to report specified information to the Department of Justice no more than 7 business days after the controlled substance was dispensed. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/26/15 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT 3/12/15	
63. CA SB 590	**Pharmacy: Intern Pharmacists** Requires, for all pharmacist licensure examination applicants, required pharmacy practice experience include experience in a pharmacy, including experience in both a community and institutional pharmacy practice setting. ISSUES: BJ*, DP LOBBYIST: CD POSITION: F	Introduced 2/26/15 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT 3/12/15 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT 4/6/15	
65. CA SB 643 **McGuire**	**Medical Marijuana** Reaffirms and clarifies aspects of the Medical Marijuana Program Act that regulates the cultivation of medical marijuana and appropriates funding for the Board of Equalization to undertake a study in order to make recommendations on the best way to levy and collect fees to regulate the cultivation and sale of medical marijuana. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F	Introduced 2/27/15 To SENATE Committee on RULES 3/12/15 From SENATE Committee on RULES with author's amendments. 04/06/2015 In SENATE. Read second time and amended. Re-referred to Committee on RULES. 04/06/2015	

67. CA SB 671 **Hill**	**Pharmacy: Biological Product** Authorizes a pharmacist, in his or her discretion, to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable and the prescriber does not personally indicate Do NOT Substitute. Requires a pharmacist or his or her designee when dispensing a biological product to communicate to the prescriber the specific biological product provided to the patient, including the name and manufacturer of the product. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: F, X	Introduced 2/27/15 To SENATE Committees on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT and HEALTH 3/12/15	
69. CA SB 715	**Investigational drugs, biological products** Permits a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with terminal illnesses. Authorizes a health benefit plan or governmental agency to provide coverage for any investigational drug, biological product, or device made available pursuant to these provisions or the associated costs. ISSUES: BJ*, DP LOBBYIST: TRT POSITION: PR	Introduced 2/27/15 To SENATE Committees on HEALTH and RULES. 3/19/15	

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

March 25, 2015

The Honorable Rob Bonta
Chair, Assembly Health Committee
State Capitol, Room 6005
Sacramento, CA 95814

SUBJECT: AB 486 (Bonilla) - SUPPORT

Dear Assembly Member Bonta:

The California Hospital Association (CHA), representing nearly 400 hospitals and health systems, is writing today in support of AB 486 (Bonilla). AB 486 ensures that centralized hospital packaging pharmacies (CHPPs) can continue to operate and serve their member hospitals efficiently.

The Governor signed AB 377 (Statues of 2012, Chapter 687) into law which established CHPP as a new licensure category and allows hospitals to create centralized hospital pharmacies that serve multiple institutions under common ownership. AB 377 also requires that medications produced in these CHPPs be barcoded, and that the barcode retrieve specific information, like medication expiration date and lot number, which can be read when scanned at the patient's bedside.

Unfortunately, a new legal interpretation of Business and Professions (B&P) Code Section 4128.4 has suggested that the specific retrievable information from the barcode be immediately viewable on a screen upon scanning the barcode. This is problematic because current technology does not allow for this function. Therefore, it has been difficult for hospitals to establish CHPPs.

In the interim, the Board of Pharmacy has created a waiver for which organizations can apply that allows the required information to be physically listed on the medication label rather than being accessible in electronic, barcode format. These waivers are only valid for a five-year term.

AB 486 requires the necessary information elements specified in B&P Code Section 4218.4 be displayed on a human-readable label or to be retrievable using a lot number or control number of the medication. In order to verify that the medication being administered is the correct medication, dosage, and route of administration for that patient, the bill would further require that a medication's barcode be machine readable using software that compares the information contained in the barcode to the electronic medical record of the patient.

AB 486 provides a long-term solution while maintaining the original intent of the law.

For the above reasons, CHA respectfully asks for your "AYE" vote on AB 486.

Sincerely,

Tanya Robinson-Taylor
Legislative Advocate

TRT:dlv

cc: The Honorable Susan Bonilla
The Honorable Members of Assembly Health Committee
Lara Flynn, Consultant, Assembly Health Committee
Peter Anderson, Consultant, Assembly Republican Caucus

San Diego Prescription Drug Abuse Task Force
2014/15 Accomplishments
SanDiegoSafePrescribing.org
SanDiegoRxAbuseTaskForce.org

THE STRUCTURE

- The San Diego **County** Prescription Drug Abuse Task Force (PDATF) is sponsored by the county, was established in 2008 and promotes collaboration between Policy, Law Enforcement, Public Health and Community. The following are some accomplishments:

- The PDA **Medical** Task Force was established October 2012, is sponsored by the County Medical Society and works in conjunction with the County task force. The task force includes internal medicine physicians, pain specialists, emergency physicians, pharmacists, dentists, the hospital association, and county health department. It includes members various medical establishments throughout the county, including Kaiser, Sharp, Scripps, UCSD, Community Clinics, Palomar/Pomerado and others.

- The PDA **Pharmacy** Committee was established in 2015 and brings together various pharmacies for collaboration with the PDATF, the Medical Task Force, and establishing best practices for pharmacies.

DATA DRIVEN

- Annual Rx Report Card
- PDMP Zip Code Data
- Medical Examiner and PDMP Data

SAFE PRESCRIBING CAMPAIGN

- **One San Diego Vision**
  Primary Care, Surgeon, ER Doc, Psychiatrist, Dentist or Pharmacist will all follow 5 principles:
  1. One provider and One Pharmacy for Chronic Medications
  2. Use PDMP
  3. Use Medication Agreements
  4. Follow the ER Safe Prescribing Principles
  5. Avoid Opioid and Benzodiazepine Combination

- Standardized Medication Agreements
  - Combination of over 30 agreements
  - Health literacy modifications
  - Promoted for all Chronic Controlled Medications

- Safe Pain Guidelines for Emergency Department
  - Based on Washington State Guidelines

- Health Literacy Modifications
-Expanded to include Urgent Cares
- Local HIDTA funded initial printing of 350,000 handouts

- Providers Pain Guidelines
  - Clinical guidelines for acute and chronic pain treatment
  - Links to educational information

- PDMP (CURES) registration drives
  - Public Health Office "deputized" to do enrollment
  - Various drives around county to increase prescriber enrollment
  - Power Point explaining ease of use
  - Medical Society and other institutions offering free notary

- Educational Programs
  - Safe Prescribing Symposium
    - interdisciplinary conference with 270 attendees
  - Webinars, Lectures to nurses, physicians, administrators about PDA epidemic

- Naloxone Promotion
  - Sherriff Program for First Responders
  - Instruction for Providers
  -Instruction for Patients
- Communications
  - Promote Safe Prescribing in San Diego news outlets via press conferences and story pitches.
  - Newsletter Publication

TO DO LIST
- Medical Examiner Office to communicate deaths to those on PDMP reports
- Best Practices for Pharmacists
- Involvement of Pediatricians
- Outreach to Psychiatrists
- Uniform approach for Safe Disposal
- Improvements with PDMP system
- Visit to San Diego by Michael Botticelli, Director of the White House Office of National Drug Control Policy
- Involvement with Health Plans

Contacts

Roneet Lev, MD, Chair of Medical Task Force, levreviews@gmail.com/ (619) 203-7190
Tom Lenox, PDATF Chair, Thomas.P.Lenox@usdoj.gov/ (858) 616-4365
Angela Goldberg, PDATF Facilitator, angelagoldberg@sbcglobal.net/760-749-8792
Sherrie Rubin, Parent Liaison, www.Hope2gether.org, 858-943-1697

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

MEDICATION SAFETY COMMITTEE MEETING SCHEDULE
2015

WEDNESDAY, JANUARY 7, 2015 10:00 AM – 2:00 PM	SACRAMENTO, CHA OFFICES BOARD ROOM 1215 K Street, Suite 800
WEDNESDAY, APRIL 8, 2015 10:00 AM – 2:00 PM	SACRAMENTO, CHA OFFICES BOARD ROOM 1215 K Street, Suite 800
WEDNESDAY, JULY 8, 2015 10:00 AM – 2:00 PM	SACRAMENTO, CHA OFFICES BOARD ROOM 1215 K Street, Suite 800
WEDNESDAY, OCT. 7, 2015 10:00 AM – 2:00 PM	SACRAMENTO, CHA OFFICES BOARD ROOM 1215 K Street, Suite 800

1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties