



DHCS 340B Self-Audit Overview

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1



Welcome

Bob Mion
Director, Publishing & Marketing
California Hospital Association



2



Continuing Education

Continuing education credits will be offered for this program for compliance, health care executives, legal and nursing.

Full attendance and completion of the online evaluation and attestation of attendance are required to receive CEs for this webinar.

3



Questions

Submit your questions through the Q & A box. (Usually located at the bottom of your screen.)

4



Faculty



Lloyd Bookman is a partner in Hooper, Lundy & Bookman's Los Angeles office. Since 1979, his practice has focused exclusively on the representation of health care providers in a wide variety of complex reimbursement, regulatory and transactional matters. He is a nationally-recognized expert on Medicare and Medicaid reimbursement and has served as lead counsel in many highly-significant cases.

5



Faculty



Joe LaMagna is a partner in Hooper, Lundy & Bookman's San Diego office. He specializes in payment disputes and government investigations. Mr. Lamagna is a co-chair of the firm's fraud and abuse practice group and regularly advises clients on potential overpayment liability, self-disclosures, and false claims act matters.

6



Faculty



Nina Adatia Marsden is a partner in Hooper, Lundy and Bookman's regulatory department. Ms. Marsden has experience assisting health care providers, including hospitals, pharmacies, and laboratories, with licensure and certification, regulatory compliance, and ownership changes. She also is experienced with Medicare reimbursement issues and assists clients in preparing appeals to the Provider Reimbursement Review Board.

7



Faculty



Ryan Witz represents members' financial interests related to Medicare, Medi-Cal, commercial payers and other government entities. Mr. Witz provides support on financial and reimbursement issues affecting California hospitals and health systems, and represents CHA with stakeholders where hospital finance and technical knowledge is needed. Ryan is also involved with the development and implementation of the hospital fee and other financing programs.

8



DISCLAIMER

- This presentation is solely for educational purposes and the matters presented herein do not constitute legal advice.
- Attendees should consult with their own legal counsel and/or risk management professional(s) for advice and guidance regarding particular situations.



9



AGENDA

- Introduction to 340B
- State Actions to Date and CHA's Advocacy
- Key History and Issues
- Compliance Requirements for Hospitals and Pharmacies



10



340B Program: Basics

PURPOSE

- Enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services

METHOD

- Manufacturers agree to provide outpatient drugs to Covered Entities at significantly reduced prices in exchange for having their drugs covered by Medicaid and Medicare Part B

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11



340B Program: Players

COVERED ENTITIES (hospitals, non-hospitals)

- Child sites
- Contract pharmacies

MANUFACTURERS

HRSA

- Apexus (Prime Vendor)

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12



340B Program: Resources

- **PUBLIC HEALTH SERVICES ACT SECTION 340(B)**
 - [42 U.S.C. Section 256b]
- **FEDERAL REGISTER NOTICES**
- **REGULATIONS**
- **HRSA WEBSITE**
 - <https://www.hrsa.gov/opa/program-requirements/index.html>
- **APEXUS WEBSITE**
 - <https://www.340bpvp.com/>

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13



340B Program: Top Enforcement Areas

ELIGIBILITY STATUS

- Covered Entity, child site, contract pharmacy

DRUG DIVERSION

- Drug dispensed based on prescription originating from ineligible site

DUPLICATE DISCOUNTS

- Medicaid discount and 340B discount

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14



340B Program: Enforcement Methods

AUDITS

- Conducted by HRSA or manufacturer

ANNUAL RECERTIFICATIONS & SELF-DISCLOSURE

- Elements of Self-Disclosure:
 - Letter to HRSA
 - Description of the violation
 - CAP
 - Strategy to work with manufacturers, including plans for financial remedy if repayment is necessary

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15



340B Program: Duplicate Discounts

The 340B Program prohibits duplicate discounts; manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug

CARVE IN

- Covered Entity will use 340B drugs for its Medicaid FFS patients
- Covered Entity must declare carve-in status via 340B registration system
- HRSA publishes Medicaid Exclusion File, identifying all such Covered Entities by name and billing number

CARVE OUT

- Covered Entity will purchase drugs for Medicaid FFS through other mechanisms (i.e., will not use 340B drugs for Medicaid patients)

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16



340B Meets Medi-Cal: The DHCS Self-Audit Request

- Welfare and Institutions Code Section 14105.46
- “You may have received overpayment by billing Medi-Cal for 340B outpatient drugs at rates in excess of AAC”
- “You may have failed to identify 340B drugs on your claims”
- Directs recipient to identify and disclose all claims submitted to 340B that it failed to flag as 340B and calculate and disclose the total amount of any overpayment

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17



State’s Actions and CHA Advocacy

- **July 2020** —DHCS distributes first wave 340B Self-Audit letters (*few hospitals*).
- **Aug. 2020**
 - CHA releases a copy of the boiler plate letter
 - DHCS hits pause on remaining letters, and grants initial blanket 90-day extensions
- **Aug. 2020 - Feb. 2021**—DHCS commits to working with CHA and based on volume of questions, DHCS begins compiling an FAQ document for covered entities who have yet to receive the letter.



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



Date

Provider Name
Provider Address
Provider Address 2

RE: DEMAND FOR SELF-AUDIT OF 340B PROGRAM OVERPAYMENTS
AUDIT PERIOD: DECEMBER 1, 2016 THROUGH DECEMBER 31, 2019
PROVIDER NAME:
PROVIDER DBA:
NATIONAL PROVIDER IDENTIFIER (NPI):

Dear Provider:

The 340B Drug Pricing Program is administered by the Health Resources and Services Administration (HRSA), and allows qualified healthcare providers, known as covered entities, to purchase outpatient drugs from manufacturers at a substantial discount. To participate in the 340B Program, covered entities must register, enroll and comply with all program requirements, including the requirement to contract with the state to dispense 340B drugs. Participating covered entities may contract with pharmacies to dispense drugs purchased through the program on their behalf. As with covered entities, federal and state requirements related to the 340B Program likewise apply to contract pharmacies. The HRSA website provides a complete list of all covered entities that participate in the 340B Program and their contract pharmacies.

Welfare and Institutions Code section 14105.46 requires covered entities to dispense 340B outpatient drugs to Medi-Cal patients, when available. If the covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal patient, but is required to maintain documentation of the inability to obtain the 340B drug. Covered entities are

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18

State's Actions and CHA Advocacy (cont.)

CA Department of Health Care Services 340B Self-Audit Request Questions & Answers

General

Q1: What is DHCS' authority to request self-audits?

A1: DHCS' authority to request a self-audit falls under DHCS' general audit authority pursuant to W&I Code Section 14105. In short, "Amounts paid for services provided to Medi-Cal beneficiaries shall be audited by the department in the manner and form prescribed by the department. The department shall maintain adequate controls to ensure responsibility and accountability for the expenditure of federal and state funds."

a. The self-audit approach is oftentimes utilized to offer auditees/providers the opportunity to satisfy program integrity (PI) expectations without the need for Audits & Investigations (AI) to perform a field visit. Nonetheless, however, the audit may be expanded depending on the results of the self-audit. This is determined on a case-by-case basis.

b. The self-audit also falls under the spirit of provider self-disclosure requirements pursuant to Social Security Act (the Social Security Act) (42 U.S.C. 1302 a-7a), established under 42 CFR Section 640.101, which requires the reporting and returning of self-identified overpayments.

Q2: Have all 340B self-audit requests been sent? If not, is there a due date for sending these requests out?

A2: DHCS' self-audit request is intended for all 340B covered entities and contract pharmacies that participate in the Medi-Cal program. There is no fixed period of time when this objective will be fully achieved. DHCS is mailing requests for self-audits in waves/phases, without a fixed period of time. DHCS currently does not have a timeframe when the next batch of request letters will be disseminated.

Q3: How does DHCS decide which covered entities and contract pharmacies to send the 340B self-audit requests to?

A3: DHCS compiled our list of impacted entities from those covered entities and contract pharmacies listed on the HRSA 340B website who participate in the Medi-Cal program.

- **Feb. 2021** — CHA provided a final set of questions to DHCS as they finalize their FAQs
- **Mar. 2021**
 - DHCS will finalize and release FAQs
 - DHCS will notify providers that have received multiple extensions due delays with issuing FAQs, they will have a definitive deadline
- **TBA**—DHCS will distribute letters to all 340B covered entities and contract pharmacies that participate in the Medi-Cal program; timing unknown

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19

W&I Code Sec. 14105.46

- Effective July 28, 2009 (sort of)
- Covered Entities must provide only 340B drugs to Medi-Cal beneficiaries
- Exception: May dispense a drug purchased at "regular drug wholesale rates" if unable to purchase a specific 340B drug; must maintain documentation of inability to purchase 340B drug
- Charge for a 340B drug cannot exceed covered entity's actual acquisition cost (AAC) plus the allowable professional fee
 - AAC is amount charged by manufacturer taking 340B discount into account
- Must identify 340B drug on claim submitted to Medi-Cal

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20



AIDS Health Foundation Case

- AIDS Health Foundation challenges 14105.46 in federal court
- District Court enjoins enforcement on May 3, 2013
- State appeals; Ninth Circuit stays district court injunction on November 14, 2014
- Ninth Circuit reverses and vacates injunction on November 8, 2016, effective December 1, 2016
- In e-mails to CHA on January 9, 2014 and September 25, 2015 DHCS says it will not enforce section 14105.46 while the appeal is pending
- This explains the December 1, 2016 lookback date

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21



DHCS Self-Audit “Demand”

- DHCS learns that covered entities may not have complied with Section 14105.46
- In July 2020, DHCS sends letters to some covered entities and contract pharmacies directing them to conduct self-audits
- Letters state recipient may have received overpayments based on a review of Medi-Cal claims for December 1, 2016 through December 31, 2019
- Cites to the 60-day report and repay rule

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22



Self Audit Demand

For the period December 1, 2016 through December 31, 2019

- Identify and disclose all claims submitted to Medi-Cal for 340B drugs which you failed to flag as 340B drugs on the claim;
- Identify and disclose all claims submitted to Medi-Cal for 340B drugs at rates exceeding your AAC;
- Identify and disclose all drugs you were unable to purchase at 340B discounted rates, that you instead purchased at regular drug wholesale rates, and eventually dispensed to Medi-Cal patients;

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23



Self Audit Demand (cont.)

- Identify and disclose all practitioners by name and NPI number who prescribed the 340B drugs which you furnished;
- Identify and disclose all 340B drug wholesalers, including account number, from whom you purchased 340B drugs;
- If you are a contract pharmacy, provide copies of all contracts you have with covered entities;
- Calculate and disclose the total amount of any overpayment;
- Requires a detailed report with an attestation that the report is “true and correct”

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24



Issues

- Does DHCS have the authority to demand a self-audit?
- Consequences if you receive an audit demand letter and don't respond?
- Should you do anything if you haven't received a letter?
- Are there any implications if the covered entity did not include the 340B code on its Medi-Cal claims but billed AAC?
- How to measure the overpayment (if any)?
- Medi-Cal managed care.

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25



Compliance Guidance Overview

- Why?
 - Duplicate discount and overpayment concerns
 - <https://www.dhcs.ca.gov/provgovpart/Pages/DrugRebateFAQ.aspx#8>
- Who has received?
- Authority of Department to request self-audit
- Self-audit process
 - Complications
- Duty to provide findings and to whom?

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26



Who Has Received?

Some discussion of all CEs receiving

- There are over 600 CEs
 - Does not seem each has received or that the letters were properly tailored
- What is obligation of CE who has not received?
 - <https://www.aha.org/initiativescampaigns/2018-09-13-340b-hospital-commitment-good-stewardship-principles>
 - <https://www.340bpvp.com/resource-center/340b-tools>; click provider type
 - [340B Oversight Best Practices Dashboard >](#)
 - » Recommends Monthly Audits
 - Regardless of receiving a letter, it has become a known issue and audits were already recommended as a “Best Practice”
 - Risk of DHCS audit, if self-audit is not conducted

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27



Self-Audit Authority

- Section 1128J(d) – colloquially “60-day rule”
- Department claims it reviewed the data and either (1) paid more than AAC, or (2) did not identify 340B drug
 - But no individualized findings presented
- 22 CCR § 51458.1 – Overpayment Audit Authority
- Prevent duplicate discounts (technically HRSA’s authority)
 - But clearly the state has an interest

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28



Self-Audit Process

- Privilege?
 - Involve counsel to direct investigation?
- Data pull with assistance of TPA
 - Need to start with good data
 - Medi-Cal Fee For Service
 - Not Medi-Cal Managed Care generally
 - Review amount billed and amount paid
 - Review presence of applicable modifier

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29



Self-Audit Process (cont.)

- Review prior audits
 - Is there an audit history?
 - https://docs.340bpvp.com/documents/public/resourcecenter/DSH_340_B_Compliance_SelfAssessment_DataTransactions.pdf
- Calculate the overpayment
 - Not necessarily AAC v. what was paid
 - Many reasons for underpayments or partial payments (duplicate bill, early refill, patient no longer Medi-Cal)
 - May need to do sampling
 - If you discover underpayments, can you offset?

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30



Self-Audit Process (cont.)

- Attestation Requested
 - No legal authority cited
 - Department has right to inspect books and records, not to create books and records
 - Provider has obligation under law to report and repay identified overpayments
 - No requirement for an attestation
 - Consequence of not submitting an attestation
 - Further audit?
 - Submit a modified attestation?

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31



Types of Issues

- Had modifier, had AAC loaded, but the modifier was not linked with the AAC rate
- Medi-Cal FFS Secondary
- Missed Medi-Cal FFS Status
- Contract pharmacy opted-out
- TPA does not have access to billing for a particular PBM to add the modifier
 - Billed AAC, but no modifier to inform the state
- Some caught it, but did not address it

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32



Reporting Issues

- CEs
 - To whom?
 - Depends on Facts
 - Was overpayment an accident?
 - When?
 - Many extensions have been granted
 - It can take time to do an internal investigation to identify and calculate an overpayment
- Contract Pharmacies
 - Department was flummoxed by carve-out process

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33



Questions

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34



Thank You

Lloyd Bookman

Hooper, Lundy & Bookman, PC.
lbookman@health-law.com

Joe LaMagna

Hooper, Lundy & Bookman, PC.
jlamagna@health-law.com

Nina Adatia Marsden

Hooper, Lundy & Bookman, PC.
nadatia@health-law.com

Ryan Witz

California Hospital Association
rwitz@calhospital.org

35



Thank You and Evaluation

Thank you for participating in today's webinar.
An online evaluation will be sent to you shortly.

For education questions, contact:

CHA Education at education@calhospital.org

36