CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

SUBJECT: CMS-1695-P, Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model, Proposed Rule, Federal Register (Vol. 83, No, 147), July 31, 2018

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS) outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2019.

CHA is very concerned that the agency's payment and policy proposals are not only unlawful, but also threaten the OPPS' financial stability — and, in turn, access to care for Medicare beneficiaries. In this rule, CMS proposes several policies that would make administering the OPPS infinitely more complicated and add significant regulatory costs and burden to providers — the very opposite of this administration's goals. We are deeply disappointed.

Based on input from member hospitals and health systems across California, CHA urges CMS:

- **To withdraw its proposals to expand site-neutral payment policies in excepted and non-excepted off campus provider-based hospital outpatient departments (HOPDs)**
- **Not to adopt its proposal to reduce payment for new Part B drugs and biologicals from wholesale acquisition cost (WAC) plus 6 percent to WAC plus 3 percent**
- **To unpackage non-opioid pain management drugs in ambulatory surgical centers (ASCs) and in HOPDs**
- **Not to pursue requiring interoperability by hospitals and other providers through compliance with a new Medicare Condition of Participation**
- **To provide additional information for hospitals on how best to meet the new price transparency requirements outlined in the FFY 2019 inpatient prospective payment system final rule**
- **To move ahead in removing proposed measures from the Outpatient Quality Reporting Program and take steps to accelerate the timeline for removal**

499 So. Capitol Street SW, Suite 410, Washington, DC 20003 • *Telephone:* 202.488.3740 • *Facsimile:* 202.488.4418
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

- **To look ahead to ensure coding, billing, cost reporting and payment decisions for CAR-T therapy are aligned and consistent. CMS should provide advance guidance about correctly reporting corresponding component services involved in providing CAR-T therapy to ensure accurate and reliable reporting.**

Our detailed comments are noted below.

Proposed Payment Reduction for Hospital Outpatient Clinic Visits in Excepted Off-Campus Provider-Based Departments

Section 603 of the Bipartisan Budget Act of 2015 (BBA) precludes payment under the OPPS for off-campus PBDs that opened after November 2, 2015, with limited exceptions; this took effect January 1, 2017. Congress subsequently enacted the 21st Century Cures Act, which exempts from the BBA payment policy additional off-campus PBDs that were mid-build. CMS generally refers to off-campus PBDs subject to Section 603 as "non-excepted off-campus PBDs." Off-campus PBDs not subject to Section 603 are referred to as "excepted off-campus PBDs." PBDs on a hospital campus are not subject to Section 603 and are simply referred to as "on-campus PBDs" or "on-campus" departments of a hospital.

In the proposed rule, CMS notes that, despite Section 603's implementation, the majority of hospital off-campus PBDs continue to receive full OPPS payment — which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. In 2019, the standard unadjusted Medicare OPPS proposed payment for the clinic visit is approximately $116; the average copayment is approximately $23. The proposed physician fee schedule (PFS) equivalent rate for Medicare payment for a clinic visit would be approximately $46, and the copayment would be approximately $9, saving beneficiaries an average of $14 per visit.

CMS believes capping the OPPS payment at the PFS-equivalent rate would remove the payment incentive that CMS believes "is driving increasing utilization" in the HOPD setting. In the proposed rule, CMS also notes that capping the rates is an effective method to control the volume of "unnecessary services."

The proposed rule references the Health and Human Services Secretary's authority under Section 1833(t)(2)(F) of the Social Security Act to develop a method for controlling unnecessary increases in the volume of covered HOPD services. To date, CMS has not established policy under this authority, instead attempting to address outpatient expenditure growth through policies such as increased packaging and the development of comprehensive ambulatory payment classifications (C-APCs). Using its authority for controlling unnecessary increases in the volume of covered HOPD services under Section 1833(t)(2)(F) of the Social Security Act, CMS proposes to pay the same amount — 40 percent of the OPPS rate — for clinic visits (G0463) at HOPDs, regardless of Section 603 exemption. CMS proposes this policy would take effect January 1, 2019.

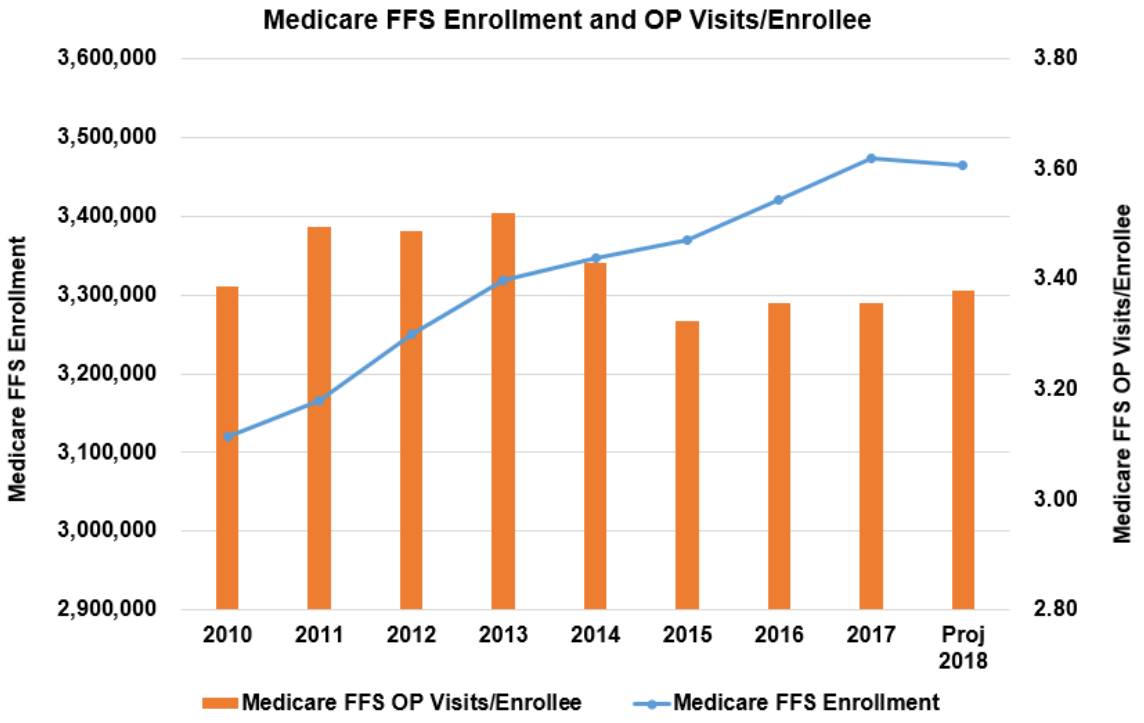
In addition, CMS does not believe that budget neutrality applies to Section 1833(t)(2)(F) of the Social Security Act and implements the proposal as a savings. The President's fiscal year 2019 budget approximates the savings — including changes in enrollment, volume and case mix — at $760 million, with $610 million of the savings accruing to Medicare and $150 million saved by Medicare beneficiaries. CHA estimates this reduction in payment will reduce hospital outpatient payments in California by $42 million for CY 2019.

CHA strongly opposes CMS' proposed policy to reduce payment for clinic visits furnished in excepted PBDs and urges CMS to withdraw this policy from any further consideration because:

- **CMS lacks the statutory authority to reduce payments to excepted PBDs, and to do so in a manner that is not budget neutral is inappropriate and contrary to the plain language of the statute.** CHA is very concerned that CMS has completely ignored congressional intent in protecting those off-campus PBDs that were open prior to November 2, 2015. Congress intended there to be a material distinction in payment rates between excepted and non-excepted PBDs — this was made clear when it exempted certain PBDs from the payment changes under Section 603 of the BBA. Congress even went so far as to further clarify which providers are excepted and non-excepted when it passed the 21st Century Cures Act, which allows providers that were mid-build to qualify for an exemption to this payment policy.

- **CMS presents zero evidence to conclude that the increased volume in the hospital outpatient setting is medically unnecessary.** Adding insult to injury, the analysis CMS articulated in the proposed rule — which it believes supports its claim of Social Security Act authority — is meaningless. CMS asserts that a major reason for the increase in off-campus PBDs is that payment under OPPS is higher than payment under other payment systems. While CMS presents some general information about hospital outpatient expenditures and volume trends, the agency has not conducted any analysis or offered other rationale specific to clinic visit volume growth. CMS provides no analysis of the trends in volume growth in other settings or compared those trends to outpatient growth, nor does CMS explore rationale for shifts in services provided across settings. Most notably, CMS presents no data showing that this increased volume is medically unnecessary and should result in payment caps that aim to reduce unnecessary expenditures.

CHA's analysis of California Medicare claims and enrollment data, detailed below, clearly demonstrates that both fee-for-service inpatient and outpatient visits and corresponding expenditures have increased — just as CMS' analysis noted. **However, compared to increased Medicare fee-for-service enrollment that occurred during the same period, it is evident that the number of outpatient visits per enrollee remained relatively flat. This does not support CMS' assertion that increasing volume equates to medically unnecessary services being provided in California. To the contrary, without the policy changes that have shifted more inpatient admissions to the outpatient setting, resulting in decreased inpatient days per enrollee, in California the number of inpatient days today would be approximately 1million more, increasing Medicare expenditures by $3.1 billion during the same time period.**



In addition, all outpatient hospital visits represent both a facility component and a professional component. A significant number of outpatient hospital visits are ordered by physicians — such as wound care, Coumadin/warfarin and other services rendered by hospitals — and billed with outpatient hospital evaluation and management codes. Increasing numbers of beneficiaries have co-morbid conditions that require these services, which are not often provided in the physician office setting. CMS presents no data or evidence related to the types of clinic visits that are being provided.

CHA members have shared the importance of their hospital-based clinics, which provide services that are not otherwise available to the community's vulnerable patient populations. The reduction in outpatient Medicare revenue to hospitals will threaten access to critical hospital-based services, such as care for low-income patients and underserved populations.

For example, Eisenhower Medical Center, located in Rancho Mirage, has a robust network of primary care clinics that provide essential services to Medicare beneficiaries across Palm Desert, Palm Springs and the Rancho Mirage area. Eisenhower Medical Center has not opened any new PBDs; all of its clinics are excepted and will now be subject to this unlawful policy, despite being excluded by Congress under Section 603 of the BBA. Under CMS' proposal, Eisenhower stands to lose more than $9.4 million in Medicare outpatient reimbursement alone. This proposal, along with other reductions in the OPPS, will result in an 8 percent decrease in outpatient payments for CY 2019. This is untenable for an independent community hospital that is struggling to continue to provide much-needed services to a significant number of elderly, medically complex Medicare beneficiaries in its community.

A 2016 study by the American Hospital Association (AHA) clearly distinguished the types of patients and services served by hospital PBDs. Relative to patients seen in physician offices, patients seen in PBDs are:

- 2.5 times more likely to be Medicaid, self-pay or charity patients
- 1.8 times more likely to be dually eligible for Medicare and Medicaid
- 1.8 times more likely to live in high-poverty areas
- 1.7 times more likely to live in low-income areas
- 1.7 times more likely to be black or Hispanic
- 2 times more likely to receive care from a nurse in addition to a physician

Patients who are too sick for physician offices or too medically complex for ASCs are treated in the PBD. Physicians refer more complex patients to PBDs for safety reasons, as hospitals are better equipped to handle complications and emergencies. As such, compared to freestanding physician offices, PBDs treat patients who are suffering from more severe chronic conditions and, in Medicare, have higher prior utilization of hospitals and emergency departments.

The absence of meaningful evidence, analysis and even the most basic data in support of this policy was discussed at length at the August 20 meeting of CMS' Advisory Committee on Hospital Outpatient Payments. We are pleased that the panel unanimously recommended that CMS **not implement** the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions (discussed below). Instead, the panel recommended that CMS study the matter to better understand the reasons for increased utilization of outpatient services, since it had not done so in the proposed rule.

Recent Policy Changes Impact Shift to Outpatient Setting

CMS ignores every plausible explanation for increased volume in the outpatient setting. Numerous payment and coverage policies implemented over the years have contributed to the current volume and expenditure growth in the outpatient setting; CMS does not address these in the proposed rule. The following are just a few of the examples of payment policies that both Congress and CMS have enacted that contribute to increased volume and expenditures.

Hospital Readmissions Reduction Program

Enacted as part of the Affordable Care Act, hospitals and health systems have actively pursued transforming the way care is delivered in one of many efforts to reduce hospital readmissions. The program's focus on six clinical areas — in addition to its support of hospital improvement and innovation networks (formerly the hospital engagement networks) — has lowered readmission rates in hospitals. In turn, this has allowed hospitals to provide medically necessary care in less costly settings, such as PBDs. This is just one of many programs that the agency has implemented in its efforts to drive value-based care for Medicare beneficiaries.

Two-Midnight Policy

After many years of inappropriate audits of short stay cases, CMS implemented the two-midnight policy. Under this policy, hospital inpatient admissions spanning at least two midnights are generally considered as reasonable and necessary for payment under Part A. An American Hospital Association (AHA) analysis has demonstrated that this policy resulted in a net shift of care from the inpatient to outpatient setting. After explicitly accounting for the decrease in inpatient stays that occurred prior to the two-midnight policy's implementation, AHA analysis showed that, in FFY 2014 alone, the two-

midnight policy resulted in a net shift of almost 200,000 inpatient stays to the outpatient setting. The Medicare Payment Advisory Commission (MedPAC) has also noted this change. Hospitals in California experienced this firsthand, as our physician partners have adopted strategies to reduce inpatient admissions under value-based contracts. As a result of the two-midnight policy and changes in the marketplace, care is increasingly shifted to the outpatient setting — a trend that was present even prior to the two-midnight policy.

Other OPPS Changes
Over the past several years, CMS has made significant efforts to move the OPPS from a fee schedule to a more true prospective payment system. In addition, it has taken steps to keep pace with changing medical practice. To date, the most notable changes that have contributed to increased outpatient volume include packaging most clinical laboratory tests into the OPPS system and changes in the inpatient-only list. Both have resulted in significant shifts in volume and expenditures in the OPPS and have not been accounted for in CMS' analysis.

CMS' Proposed Changes Jeopardize Beneficiaries' Access to Care
MedPAC recently noted in its March 2018 report that overall Medicare margins were at a record low of negative 9.6 percent in 2016, with a new record low of negative 11 percent projected for 2018. In California in 2016, Medicare total margins were negative 19.3 percent, and outpatient Medicare margins were negative 19.9 percent — far below the national average. Even MedPAC's analysis of "efficient" hospitals had a negative margin in 2016, for the first time since it began its "efficient hospital analysis." **The site-neutral payment policies implemented by CMS for 2017 and beyond will further reduce these margins.** CHA is very concerned that the unlawful expansion of site-neutral payments to clinic visits will destabilize an already fragile OPPS system and threaten beneficiary access to critical hospital-based safety-net services.

Moreover, CMS has failed to recognize the importance of a stable inpatient and outpatient payment system in supporting hospitals' ability to adequately fund their 24/7 emergency standby capacity. **CMS must not ignore that the hospital safety net and emergency standby role are funded through the provision of all inpatient and outpatient services.**

Finally, CHA is deeply concerned that CMS' policy is based on the flawed assumption that Medicare physician rates are adequate to cover the costs of providing care to Medicare beneficiaries. However, hospitals and health systems across California note that the continued erosion of both Medicare and Medicaid payments, the added regulatory burdens of a new physician payment system and the push to keep pace with electronic health record (EHR) technology make it challenging for physicians to maintain their independent private practice. While California state law prohibits physician employment, it does allow for the establishment of a 1206(d) clinic that operates as a provider-based HOPD. In California, this is not an easy health care transaction — in fact, it is quite complicated and implementation is incredibly expensive. Therefore, it is not the first method by which hospitals seek to align and integrate with physicians. Rather, physicians often express to their hospital and health system partners their inability to continue to practice in the community without hospital support. For example, Southern California physicians with a full Medicare practice who perform — based on relative value units — at the national volume median would earn approximately $164,000 per year in take-home pay, plus $18,000 in benefits. In comparison, the national median compensation level for internal medicine is $250,000, inclusive of salary and benefits. The amount earned by physicians in Southern California is closer to the

compensation for nurse practitioners and other physician extenders in this region of the country. This disparity, in addition to the costs of complying with Medicare regulations, makes it increasingly challenging to attract and retain physicians in areas — like Southern California — with high Medicare use. Physicians look to hospitals to integrate and support their continued ability to stay in these communities and serve their patients. Many physicians find themselves unable to make private practice work due to the payer mix in some of our most vulnerable communities.

CHA urges CMS to withdraw this policy. Such an approach only contributes to the unsustainable cost shift and erodes hospitals' and health systems' ability to continue to meet beneficiary needs while meeting the agency's goals of transforming our delivery system for the future.

Expansion of Site-Neutral Payment Policies to Clinical Families of Services at Excepted Off-Campus PBDs

In the CY 2019 proposed rule, CMS again expresses concern that allowing expansion of services in excepted off-campus PBDs incentivizes hospitals to purchase additional physician practices and add those physicians to an existing excepted off-campus PBD, in a manner that the agency believes is inconsistent with Section 603's intent. As such, CMS proposes to revise the definition of "excepted items and services" to apply only to those services from clinical families of services from which the excepted off-campus PBD furnished a service (and subsequently billed for that item or service under the OPPS) during certain baseline periods (generally from November 1, 2014, through November 1, 2015). CMS proposes 19 families of service for use in making this determination.

To comply with this proposed policy, CMS would require excepted off-campus PBDs to ascertain the clinical families of services from which they furnished services during the baseline period. Any items and services furnished by the excepted off-campus PBD after the baseline period that are not among the families of service furnished and billed under the OPPS during the baseline period would no longer be excepted services. Instead, starting January 1, 2019, such services would be required to be reported with modifier "PN," indicating non-excepted services paid under the PFS. CMS also notes that items and services not identified among the 19 families of services included in the proposed rule that are furnished by excepted off-campus PBDs would also be non-excepted services paid under the PFS.

CHA urges CMS to withdraw this proposal. We strongly oppose its implementation for reasons cited in previous rulemaking, as well as additional considerations that have developed after two years of the current policy's implementation.

First, throughout the 2017 OPPS proposed and final rules that implemented Section 603, CMS references the provider-based regulations found at 42 CFR 413.65. These regulations define a department of a provider as follows:

> Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility.

This **existing** definition is consistent with how hospital departments operate; the requirements for provider-based status are designed to ensure integration with the main hospital. Further, the regulation clearly states that PBDs are specifically designed to furnish health care services of the same type as those furnished by the main provider. This is also evidenced by CMS' preamble discussion with the initial PBD regulations, which states "[W]e emphasize that the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole. That is, the facility in its entirety must be a subordinate and integrated part of the main provider." (67 FR 50088)

Since the beginning of PBD determination, the concept has been based on PBD status being assigned to the department as a whole — not the individual "items and services." This approach must be maintained, as it is foundational to how hospitals operate and deliver health care. CMS' proposal fundamentally changes — and makes infinitely more complex — the provider-based rules and requirements. Moreover, hospitals and health systems have described implementation of this proposed policy as incredibly costly, administratively burdensome and absolutely not feasible for a January 1, 2019, effective date.

As stated in previous rulemaking, if finalized, this policy would essentially freeze excepted PBDs, taking away their ability to adapt to meet the changing needs of their patients. Further, it would stifle innovation and care transformation. Most concerning is the impact on our rural communities, whose aging population requires an ever-changing health care system to support beneficiaries' desire to "age in place." These excepted PBDs have been essential to attracting and retaining specialty providers in rural communities, but the health system must continue to evolve as its population evolves.

One large health system shared that the costs of implementing such a policy would be significant and create administrative burdens that would continue to drive up costs long after implementation is complete. The initial costs of identifying services during a baseline period would take significant personnel resources, including data mining. To conduct this analysis, every hospital with one or more excepted off-campus PBDs would have to retrieve claims data from three to four years ago and, for each claim during the baseline period, determine exactly in which location each covered service was furnished (including claims that contain multiple services furnished in multiple locations). Then, separately for each location that is an off-campus PBD, the hospital would have to sort these services into their designated APCs and then into their clinical families. This exercise would require hospitals to crosswalk certain services that may have had changes in their Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology (CPT) codes or APC assignments since the baseline period. Notably, the HCPCS, CPT and APC assignments change every year.

Once the hospital determines exactly which services, APCs and clinical families its off-campus PBDs furnished during the baseline period, it would then have to create, test and implement a process by which it could correctly apply the "PO" or "PN" modifier to each service it will furnish in each of its excepted off-campus PBDs starting on January 1, 2019. Since different excepted PBDs will have furnished different services during the baseline period, this process would have to be customized for each excepted off-campus PBD.

The added costs of updating every single PBD's billing system to account for specific service lines and the applicable modifiers will result in nothing but a financial windfall for vendors who will have to painstakingly make changes at each PBD location to secure compliance. Further, it would be impossible

to obtain the financial and personnel resources needed to ensure compliance by January 1, 2019. This policy is fraught with administrative burden and costly changes that will only drive up the cost of care. CHA urges CMS to withdraw this policy.

Continuation of 340B Payment Cuts and Extension to Non-Excepted Off-Campus PBDs

Congress established the 340B Drug Pricing Program 25 years ago to provide safety-net hospitals financial relief from high prescription drug costs. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals that serve low-income and indigent populations. **In California, 175 hospitals across more than 1,800 sites participate in the 340B program. These hospitals rely on 340B savings to not only reduce the price of lifesaving pharmaceuticals for vulnerable patients, but also expand additional health services throughout the community**.

In the OPPS final rule for CY 2018, CMS reduced payment for separately payable drugs without pass-through status that are purchased under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. However, payment for Part B drugs that would otherwise be separately payable under the OPPS, but are not because they are furnished by non-excepted off-campus outpatient provider-based departments (PBDs), continue to be paid at ASP plus 6 percent, consistent with Part B drug payment in the physician's office. In the OPPS proposed rule for CY 2019, CMS proposes to continue the 340B payment cuts that were finalized in 2018 and extend the ASP minus 22.5 percent payment reduction to 340B drugs furnished in non-excepted, off-campus PBDs.

CHA strongly opposes CMS' proposed continuation of the 340B payment cuts and extension of the payment cuts to non-excepted, off-campus PBDs. CHA respectfully requests that CMS withdraw these proposals from consideration, as they fundamentally undermine the program's intent and goals and will have devastating impacts on patients served by 340B hospitals and clinics. Furthermore, we disagree with CMS' assertion that 340B hospitals will move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs in the absence of this policy change. We urge CMS to study hospitals' drug administration behavior pre- and post-implementation of the 2018 OPPS final rule to confirm this presumption before finalizing such an extreme policy.

Congress intended for savings from the 340B program to help participating entities "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Many 340B hospitals are the safety net for their communities, and the 340B program generates valuable savings to reinvest in programs that enhance patient services and access to care.

CMS notes that it found 115 unique, non-excepted off-campus PBDs that billed for separately paid drugs acquired under the 340B program. Further, CMS notes that this proposal would save the Medicare program $48.5 million for CY 2019 — an average payment reduction of over $421,000 for each non-excepted off-campus PBD. CHA is concerned that this type of payment cut is not sustainable and may force many of these facilities to reduce services or close. This is particularly concerning in rural and underserved areas where urban 340B hospitals operate off-campus clinics. The proposed policy would

deter 340B hospitals from expanding off-campus clinics that primarily administer drugs, such as infusion therapy clinics, into rural and underserved areas.

For example, several 340B hospitals that operate infusion therapy centers in rural areas said that, without the 340B discount, they could not afford to keep these clinics open. Due to skyrocketing pharmaceutical prices, many physician practices cannot afford to own and operate infusion therapy clinics in California — meaning that some of the sickest patients undergoing chemotherapy treatment in rural California may have to travel 30 to 40 miles to the nearest infusion therapy center.

Similarly, inner city clinics operated by 340B hospitals are also financially unviable and depend greatly on savings generated from the 340B drug discount program. Many inner city clinics operate with the purpose of reaching patients suffering from diabetes, HIV and Hepatitis C. If implemented, the proposed Medicare reimbursement rates for Part B drugs would require many California hospitals to close these financially vulnerable clinics. As a result, the provision of routine, necessary care to these vulnerable patient populations would be severely compromised.

It is quite concerning that the proposed 340B policy change does nothing to address the unsustainable increases in the cost of drugs. If the average sales prices for pharmaceuticals in our country were reduced, the cost to the Medicare program and its beneficiaries would also be reduced. CHA urges CMS to focus its attention on the underlying issue of rising pharmaceutical costs as opposed to unsustainable cuts to Medicare payments to a subset of safety-net hospitals.

The 340B program is vitally important to the nation's safety net. We believe that alternative approaches could address the issue of rising drug prices, and we will work with the administration and Congress in support of alternatives**. In the interim, CHA urges CMS to protect the 340B program and withdraw the proposal to continue the 340B payment cuts and expand the payment cuts to non-excepted, off-campus PBDs. Since 1992, this bipartisan program — which does not depend on taxpayer dollars — has allowed hospitals to access discounted drugs, enabling them to stretch scarce federal resources and provide more comprehensive services.** The cuts proposed by CMS are contrary to the program's statutory intent — to help covered entities and the vulnerable populations they serve. The proposed changes will penalize safety-net hospitals participating in the 340B program and severely impede their ability to sustain vital services and care for patients in California's most underserved communities.

Proposed Payments for Biosimilar Biologics Acquired Under the 340B Program

For CY 2019, CMS proposes to change the Medicare Part B drug payment methodology for biosimilars acquired under the 340B program. Specifically, the agency proposes to pay non-pass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar's ASP, instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. While CHA appreciates that this proposed policy change will result in a marginal payment increase for non-pass-through biosimilars acquired under the 340B program, we continue to have concerns with the overarching policy to reimburse 340B hospitals at ASP minus 22.5 percent as opposed to ASP plus 6 percent.

Exclusion of Procedures Assigned to New Technology APCs From C-APC Packaging

CHA supports CMS' proposal to exclude procedures assigned to new technology APCs from being packaged into C-APCs and agrees with CMS' concern that packaging payment reduces the number of claims for the new technology that are available for APC pricing. The proposed rule indicates that

packaging in this circumstance is contrary to the objective of the new technology APC payment policy, which seeks to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

Changes to Packaged Items and Services

In the proposed rule, CMS discusses its packaging policy for 2019 in response to a report from the President's Commission on Combating Drug Addiction and the Opioid Crisis. The commission recommended that CMS "…review and modify rate setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain." The commission's concern is that the policy incentivizes prescription of opioid — rather than non-opioid — medications to patients for post-surgical pain.

We agree that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and, therefore, warrants separate payment under *both* the OPPS and the ASC payment system. As a result of declining utilization of Exparel in the ASC setting once the drug stopped receiving pass-through payment, CMS proposes to unpackage and separately pay for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. While this proposal is a departure from CMS' current ASC packaging policy for drugs that function as a supply, CMS believes the proposed change will provide incentives to use non-opioid pain management drugs with surgical procedures in the ASC setting and is responsive to the commission's recommendation.

CHA supports this proposal, but also recommends that CMS similarly unpackage Exparel and other non-opioid pain management treatments in hospital outpatient departments. We agree that this strategy could incentivize use of non-opioid pain management drugs in all settings in which outpatient surgery and other outpatient services involving pain management are furnished (such as in the emergency department). While certainly not a solution to the opioid epidemic, unpackaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-standing practice patterns without major negative consequences. CHA urges CMS to be consistent in its payment policies across settings. Finally, CHA supports CMS' efforts to **unpackage other non-opioid treatments, including drugs, devices and therapy services that are not currently separately payable in both the ASC and hospital outpatient department settings.** Specifically, CHA supports the AHA's comments recommending separate payment for items such as continuous infusion pumps, Polar ice devices, etc.

Chimeric Antigen Receptor T-cell Therapy

Chimeric antigen receptor T-cell (CAR-T) therapy is a new cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. As a new technology involving multiple steps across potentially different providers, it is important that appropriate clinical codes be available to report, identify and correctly reimburse the different component services involved in providing CAR-T therapy.

Recently, the American Medical Association approved four CAR-T-related category III CPT codes, effective January 1, 2019. These codes capture the harvesting of blood-derived T lymphocytes, preparation of the cells (e.g., cryopreservation, storage), and receipt and preparation of CAR-T cells for administration. In addition, the National Uniform Billing Committee approved a new revenue code and

value code for reporting cell/gene therapy services, including CAR-T. The new codes, which take effect April 2019, would capture services associated with the acquisition of the cells, storage, and infusion/insertion of the manipulated biologic (modified cells). They would also provide CMS and other health plans with an opportunity to examine the associated costs directly related to these therapies.

Given the newness of the CPT, revenue and value codes, there is currently a potential overlap with existing Q codes. To our knowledge, HCPCS Q or J codes have not been revised to exclude the clinical services covered by the new codes. **We urge CMS to coordinate across relevant CMS departments and decision-makers to ensure coding, billing, cost reporting and payment decisions for CAR-T therapy are aligned and consistent. Instructions should then be provided to guide the correct reporting of the corresponding component services involved in providing CAR-T therapy. Such guidance should also include the proper reporting of dosage for pediatric vs. adult indications.**

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost-Based Payments

Many Part B drug payments are based on the ASP methodology and, by statute, include an add-on payment of 6 percent of the ASP amount. Some Part B drugs are based on wholesale acquisition cost (WAC), such as single-source drugs without ASP data. The add-on percentage for drug payments is typically applied to the ASP; in certain situations, the same 6 percent add-on is also applied to the WAC for Part B drug payments.

CMS notes that the MedPAC and others, including the Office of the Assistant Secretary for Planning and Evaluation and the Office of Inspector General, have raised concerns about the use of a 6 percent add-on payment for both ASP and WAC, which may create an incentive to use them. The June 2017 MedPAC report to Congress included a recommendation to reduce WAC-based payment to WAC plus 3 percent.

In response to those concerns, CMS proposes that, effective January 1, 2019, WAC-based payments for Part B drugs utilize a 3 percent add-on payment in place of the 6 percent add-on payment that is currently applied. CMS notes this proposal does not include WAC-based payments for single-source drugs under the provision of the statute that specifies that the payment is 106 percent of the lesser of ASP or WAC. In addition, this proposed policy would not alter the OPPS payment limit (95 percent of the published average wholesale price). **CHA strongly opposes this proposal for several reasons and believes it is nothing more than a blunt instrument to cut critical payments to providers, rather than taking the necessary steps to fundamentally address the rising cost of prescription drugs.** MedPAC's recommendations, which CMS cited in its rationale for this proposal, were part of a larger set of sequential steps the agency and Congress should consider in the future; they were not intended to be a standalone solution.

First, the proposed reduction in payment ignores the current sequestration cut of 2 percent on separately payable Part B drugs. This cut effectively reduces current payments to WAC plus 4 percent, not WAC plus 6 percent. Further reduction in payment is unwarranted when the agency has not yet taken steps to address the lack of accurate and reliable ASP data. Due in part to this lack of data, CMS has no choice but to base payment on a drug's WAC — which MedPAC notes is a potentially inflated measure of price.

More specifically, MedPAC notes in the June 2017 report that CMS should take immediate action to improve the ASP system in 2018 by requiring all manufacturers of products paid under Part B to submit ASP data; MedPAC also recommends penalties for those that fail to report. MedPAC notes that not all manufacturers are required to report ASP data. Therefore, those without Medicaid rebate agreements with states are exempt from reporting. This is a long-standing issue and one that CMS should address before setting forth additional proposals to decrease provider payments to providers.

In addition, CMS has taken no action to date to ensure the currently reported data are reliable and valid. The MedPAC analysis demonstrates the decrease in ASP over time, from quarter to quarter, but — because of the lag in data reporting — those decreases are not reflected in a timely fashion, which leads to inaccurate payments. CMS should take action to create a more timely and robust reporting system. ASP can change quickly; the data would be greatly improved by increasing reporting requirements for manufacturers, shortening the reporting time frames to account for the delay, and increasing oversight and analysis to ensure accurate reporting. While CMS notes its proposal does not include WAC-based payments for single-source drugs under the provision of the statute that specifies that the payment is 106 percent of the lesser of ASP or WAC, improving the data would only further improve payment accuracy.

CHA shares the administration's concerns that addressing the cost of prescription drugs is a top priority. However, the current proposals do nothing to address the root causes of rising drug prices. We ask CMS to withdraw this policy and work with stakeholders to develop more robust solutions that address the issue's foundation.

Hospital Outpatient Quality Reporting Program

CHA fully supports CMS' efforts to reduce the number of hospital outpatient measures as part of its Meaningful Measures Initiative, and applauds the agency for its consideration of the field's comments related to the challenges surrounding implementation. **In the CY 2019 OPPS rule, CMS proposes to remove a total of 10 measures from the Outpatient Quality Reporting (OQR) Program — one starting with the CY 2020 payment year (based on 2018 provider performance) and nine starting with the CY 2021 payment year (based on 2019 performance). CHA supports CMS' proposal and urges the agency to consider an earlier removal timeline for the nine measures slated for removal in CY 2021 for several reasons.**

The OQR program has long been challenged in providing meaningful information on hospital outpatient care to consumers. In addition, its measures have not been used for meaningful performance improvement activity in hospitals. Developing claims-based measures that apply to both a physician office and hospital outpatient setting has not been achievable. The challenges of implementation are significant in light of the differences in patient mix, services provided and fundamentally different Medicare claims processes. These factors combine to make the measures adopted in other settings unfeasible and unusable in the hospital outpatient setting. **The burden and costs associated with these measures are far greater than any measureable improvement seen to date. We believe it is appropriate to remove the additional nine measures for this calendar year — rather than next year, as proposed — in an effort to reduce agency and provider burden.**

We are pleased CMS has chosen to weigh the often-significant provider and clinician information collection and reporting burden associated with quality measurement usefulness in Medicare programs.

As part of its focus on reducing regulatory burden, CMS proposes to add a new measure removal factor to its previously finalized list of seven factors. The proposed Factor 8 would allow the removal of a measure for which CMS has determined the costs associated with a measure outweigh the benefit of its continued use in the program. **CHA fully supports the addition of proposed Factor 8.**

Finally, we continue to be concerned that several measures that remain in the OQR program do not have or have lost National Quality Forum (NQF) endorsement. The absence of NQF endorsement indicates that a measure lacks several important characteristics that allow it to be meaningful to patients and acted upon by providers. **CHA urges CMS to consider NQF endorsement as a ninth measure removal factor. Like the other removal factors, lack of NQF endorsement would not automatically result in a measure's removal; a measure may be retained if it addresses an important area of care not otherwise evaluated or if removing the measure would result in decreases in quality.** To that end, CHA believes there are additional measures in the OQR program (e.g., OP-2, 8, 10, 22 and 33) that CMS should strongly consider for removal. In addition, we urge CMS to continue in its work to assess measures for the impact of sociodemographic factors on performance and incorporate adjustments where needed.

Inpatient Quality Reporting Program Policies

CHA strongly supports CMS' proposal to remove the three "communication about pain" questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with 2022 discharges (for FFY 2024 payment).

Although CMS states that is not aware of any scientific studies that support an association between scores on the communication about pain questions and opioid prescribing practices, we agree that they are appropriate for removal under an abundance of caution. **We also believe CMS can take steps to accelerate their removal from the program. Under the current proposal, the questions would be removed effective with January 2022 discharges, for the FFY 2024 payment determination and subsequent years.**

CMS notes that it considered proposing earlier removal of the questions, but proposes January 2022 to allow sufficient time to make needed updates to the data collection tools — including the CMS data submission warehouse and related reporting tools — and to update the survey instrument itself. In addition, CMS believes the later data would allow time to assess the impact of using the questions while monitoring unintended consequences and empirical testing of how removal of these questions might affect responses on other survey items. CHA appreciates CMS' consideration of the number of factors that must be contemplated prior to removal of the questions. However, we respectfully request that CMS take any steps necessary to accelerate their removal and engage stakeholders directly about public reporting considerations.

Request for Information on Promoting Electronic Interoperability

CMS seeks feedback on promoting interoperability and, specifically, how it could use the Medicare and Medicaid Conditions of Participation (CoPs) to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, the agency might require that hospitals electronically send discharge information to a patient's community provider

when possible, and provide discharge instructions electronically to patients or a third-party application, if requested.

CHA appreciates the work undertaken by CMS in recent years to promote a regulatory framework for the Medicare CoPs, which supports our collective goals of high-quality, patient-centered care in a rapidly changing health care delivery system. **However, CHA opposes the creation of additional CoPs to promote interoperability of electronic health information.**

Recent changes in law have demanded more fully integrating health care services, putting the patients' health, safety, well-being and preferences at the forefront. The hospital CoPs in particular are still in need of updating, as many have not kept pace with changes in care delivery or hospital and health system organization and integration. Our regulatory framework must more fully address these changes in both the acute and post-acute care settings. Should CMS proceed down this path, we urge the agency to look more broadly at all the CoPs and prioritize all contemplated revisions. **A piecemeal approach that does not consider implications across the delivery system will likely lead to the need for additional revisions sooner rather than later. The CoPs must be looked at in total, through a shared lens of overarching and agreed-upon principles — not in silos.**

To that end, we request that CMS take this opportunity, under a relatively new administration, to demonstrate leadership in this area and consider a more formal stakeholder engagement process as part of its Patients over Paperwork Initiative. With the initiative's goals as the framework for engagement, working with providers across the continuum of care on a more refined set of guiding principles will assist the agency in prioritizing its work so that providers can anticipate and prepare for what will likely be significant revisions to the CoPs — along with anticipated payment and other regulatory changes that, if not timed sequentially, will pose significant operational and financial challenges. An opportunity to share our perspectives, offer suggestions and participate in an ongoing dialogue about these and other changes with the agency would help foster better understanding and shared expectations, and would allow the field adequate preparation time.

Any revisions, additions or removal of CoPs — regardless of the care setting to which they apply — must address not only the current way care is delivered, but also future care delivery. It is imperative that the development of interpretive guidance be done in consultation with revisions to the CoPs. Surveyor training and oversight of the process must be a top priority for the agency. CHA looks forward to working with CMS on these and other CoP changes.

In response to CMS' more specific request for comments, CHA has previously noted that we support policies and practices for effective and sustainable transitions of care, and commend CMS' previous efforts to update existing CoPs to align with current practices and to clarify expectations of providers. However, we continue to believe appropriate oversight must be balanced with the need for flexibility and innovation, and keeping pace with the current state of health information technology (HIT).

CHA believes it is premature for CMS to consider requiring interoperability of providers until all have an effective EHR system and can participate effectively in the electronic exchange of information. Before CMS considers revisions to the CoPs that would require electronic transfer of health information, it must survey the HIT landscape of the entire health system, not just that of acute care hospitals. While hospitals and health systems have made great strides in the adoption of EHRs under the Medicare and

Medicaid EHR Incentive programs, and continue the work under the Promoting Interoperability programs, the use of EHRs is not as widespread in other care settings, including many physician offices. Some of the most critical junctures for the exchange of health information are during transitions to care settings such as post-acute and behavioral health providers, who were not incentivized to adopt certified EHR technology under the meaningful use programs. As a result, it is often not possible to effectively exchange electronic information with these providers.

CMS must also understand additional operational challenges that currently present barriers to interoperability. Due to a lack of standardized patient identifier, hospitals continue to have challenges in patient matching. Hospitals experience major challenges in transferring health information for medically indigent patients, who often do not have a primary care provider and may not have a permanent address.

Hospitals also often lack the appropriate contact information when transferring health information to community providers or payers. Section 4003 of the 21st Century Cures Act requires the Health and Human Services Secretary to "directly or through partnership with a private entity, establish a provider digital contact information index for providers and facilities." To date, this digital contact information index has not been established. **CHA urges CMS to work with the Department of Health and Human Services to develop this directory as soon as possible. Until the government helps providers solve the problems of patient matching and fully implements a system of accurate provider and payer contact information, hospitals must choose between complying with federal requirements and opening themselves up to risk of penalty under state and federal law for a privacy breach if protected health information is inadvertently sent to the wrong place or provider. That penalty, in California, comes with a significant fine.**

Any future changes to requirements for electronic transfer of health information must also consider the various legal barriers to increased sharing of health information. In comments on CMS' previously proposed changes to the regulations at 42 CFR §482.13, CHA noted that we believe proposed revisions to the CoPs on patients' right to access their own health information are unnecessary and further confuse the body of law surrounding health information privacy. The Health Insurance Portability and Accountability Act (HIPAA) currently requires hospitals to provide patients access to their medical information with limited exceptions, including certain medical records related to research; prisoners' records where access might jeopardize the health or safety of the patient or other inmates; mental health records where access is reasonably likely to endanger the life or physical safety of the patient; and psychotherapy notes.

Portions of existing regulation (42 CFR Part 2) restrict sharing of substance use disorder (SUD) information, which further complicates the exchange of health information in some cases. Clinicians treating patients for any condition need access to their complete medical histories — including information related to SUD — to ensure their patients' safety and delivery of the highest quality care. Partitioning a patient's record to keep SUD diagnoses and treatments hidden from the clinicians entrusted to care for them, as required by 42 CFR Part 2, is dangerous for the patient, problematic for providers and contributes to the stigmatization of mental and behavioral health conditions. To ensure compliance with 42 CFR Part 2, clinicians must maintain two separate computer systems and two separate medical records. This requirement adds burden and expense, but without benefit. CHA supports efforts to make statutory changes that would amend 42 CFR Part 2 to align with HIPAA for the

purposes of treatment, payment and health care operations. Such changes are required before hospitals and other community providers can meaningfully share health information.

These and other issues must be considered both through notice and comment rulemaking, as well as through stakeholder dialogue. CHA stands ready to work with the agency to identify the challenges and opportunities, and solve problems together. Our goals are shared, and we urge CMS to make this a priority going forward. There is tremendous opportunity to advance the regulatory framework in which care is provided, lower costs and decrease burden and — most importantly — make our health care system more patient-friendly.

CHA appreciates the opportunity to comment on the CY 2019 OPPS proposed rule. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs