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October 5, 2020

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

RE: CMS-1736-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Proposed Rule, Federal Register (Vol. 85, No.156), August 12, 2020

Dear Administrator Verma:

The University of California Health system appreciates this opportunity to provide comments on the Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2021 proposed rule (CMS-1736-P). The University of California's health system is comprised of six academic health centers located at Davis, Irvine, Los Angeles, Riverside, San Diego, and San Francisco, which are collectively known as UC Health.

UC academic health centers provide tertiary and quaternary specialty services to critically ill patients throughout California, and beyond, and serve as critical safety net providers. Each UC academic health center participates in the 340B Drug Pricing Program, and the benefits of this outpatient prescription drug program have allowed UC academic health centers to provide an array of comprehensive services to low income, uninsured and underinsured patients in California that otherwise would not be financially sustainable, such as:

- Free medications upon discharge for uninsured patients or patients who meet established financial need criteria
- Free health screenings in public schools and other community locations to benefit homeless and low- income populations Level 1 (adult and pediatric) trauma, burn and emergency services
- Access to specialty services clinics in remote and underserved areas, including low income individuals or the homeless in the 340B participating hospital's community
- Clinical pharmacy services to patients with serious medical conditions such as HIV to improve medication adherence and patient outcomes.

UC academic health centers are members of the American Hospital Association, the California Hospital Association, America's Essential Hospitals, and the Association of American Medical Colleges, and UC Health supports many of the comments offered by those organizations to the proposed rule.

UC Health is **deeply concerned** about the steep cuts CMS is proposing apply to hospitals enrolled in the 340B Drug Pricing Program. UC Health continues to oppose reimbursement cuts for 340B-acquired drugs. Further reductions to the reimbursement for 340B-acquired drugs will negatively impact safety net hospitals' ability to serve their vulnerable communities, as was intended when the 340B Drug Pricing Program was established. Additionally, these cuts come at a particularly unfortunate time, as UC Health recovers from over **$1 billion** in net revenue loss incurred during the COVID-19 pandemic. More importantly, **UC Health relies on 340B savings to not only reduce the price of lifesaving pharmaceuticals for vulnerable patients, but also to expand additional health services throughout California's communities.**

UC Health has concerns about certain policies in the proposed rule, including:

- ***340B Drug Pricing Program.*** UC Health respectfully requests that CMS restore payment for separately payable drugs acquired through the 340B Drug Pricing Program at average sales price (ASP) plus 6%.
- ***Inpatient Only (IPO) List.*** CMS should delay finalizing the elimination of the IPO List and solicit stakeholder feedback to evaluate which procedures are appropriate to be performed in the outpatient setting to ensure beneficiary safety and successful outcomes.

These concerns are explained in more detail below.

340B Drug Pricing Program

CMS is proposing to further reduce reimbursement for separately payable drugs paid under the OPPS and acquired through the 340B Program beginning January 1, 2021. CMS is basing this reduction on a spring 2020 survey sent to 340B hospitals during the public health emergency (PHE) for which the Agency received responses from slightly more than half of the hospitals surveyed. This survey does not accurately reflect the hospitals that participate in the 340B Program, nor the drugs acquired under the 340B Program and should not be the basis of further reimbursement cuts. **UC Health believes that CMS does not have the legal authority to impose cuts on only a subset of hospitals participating in OPPS, and we continue to strongly oppose reimbursement cuts to hospitals for 340B-acquired drugs.**

Survey

CMS sent hospitals participating in the 340B Program a voluntary survey during the initial weeks of the pandemic to gather information on acquisition cost data for drugs purchased under the 340B Program.

CMS gave hospitals two options to complete the survey: a Quick Survey using 340B ceiling prices and a Detailed Survey. Our hospitals chose the Quick Survey option, as it was not possible to complete the Detailed Survey within the three-week time frame provided, particularly during a time when many of our staff were already working long hours to address the COVID-19 public health emergency. We simply could not calculate 340B volume weighted average acquisition costs for more than 400 codes under Medicare's Healthcare Common Procedure Coding System (HCPCS), which encompasses 1,100 national drug codes (NDCs) and would require converting NDC purchase units to HCPCS dosage units. These tasks would take a significant amount of time by hospital staff who already are consumed responding to the COVID-19 pandemic. Given the burden, the lack of clear instructions on how to calculate volume weighted average acquisition costs, and the short turnaround time while we are addressing the COVID-19 public health emergency, the Detailed Survey was not possible for any of our hospitals.

As a result, our hospitals elected the Quick Survey option, which required only checking a box to indicate that we "prefer that CMS utilize the 340B ceiling prices obtained from the Health Resources and Services Administration (HRSA) as reflective of your hospital acquisition costs." We also wrote separately to CMS to make clear that in selecting the Quick Survey option, our hospitals were acknowledging only our preference for the less-burdensome Quick Survey as opposed to the Detailed Survey, as a method for estimating the acquisition costs of "covered outpatient drugs." This was not intended to be an acknowledgment, attestation, or certification that the 340B ceiling prices exactly match each hospital's 340B drug acquisition costs.

Despite this explanation that our hospitals, and we believe many other hospitals provided, we understand that CMS continued to use 340B ceiling price as a proxy for the hospital's acquisition costs for these drugs. Moreover, CMS has said that where the acquisition price for a particular drug was not available, not submitted, or if the hospital did not respond at all, CMS used the 340B ceiling price for that drug as a proxy for the hospital's acquisition costs. Based on CMS' analysis of the results of this survey, CMS claims that the "typical acquisition cost for 340B drugs for hospitals paid under the OPPS is average sales price (ASP) minus 34.7 percent." CMS is proposing an add-on payment of 6 percent of ASP for services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. Therefore, CMS is proposing a net reimbursement of ASP minus 28.7 percent for 340B-acquired drugs beginning January 1, 2021, an increased cut from the current ASP minus 22.5 percent.

Payment Policy

In the CY 2018 OPPS final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5%, instead of ASP plus 6%. In 2019, CMS continued this policy and expanded it to apply to off-campus provider-based departments (PBDs) that are subject to section 603 of the Bipartisan Budget Act of 2015 and paid under the Physician Fee Schedule (PFS)-equivalent rate equal to 40% of the OPPS payment amount. For CY 2021, CMS proposes to modify its payment policy and pay for separately payable drugs acquired through the 340B program at ASP minus 34.7%, plus an add-on of 6% of the product's ASP, for a net payment rate of ASP minus 28.7%.

UC Health strongly opposes CMS' proposed payment methodology for 340B purchased drugs and respectfully requests that CMS restore payment for separately payable drugs acquired through the 340B program at ASP plus 6%. As it stands, CMS' current and proposed payment rates fundamentally undermine the program's intent and goals and will have devastating impacts on patients served by 340B hospitals. These efforts by CMS subvert the congressional intent of the 340B Program that allows safety-net hospitals to invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients. UC Health also wishes to emphasize that CMS has drastically underestimated the financial impact on hospitals if this were to go into effect. **The impact of proposing an additional 6.2% reduction would be an estimated $8 million loss per year to UC Health, at a time when UC Health hospitals, like so many other safety net providers, are already stretched thin.**

Inpatient Only List
CMS proposes to eliminate the IPO list in its entirety (all 1,740 services) by January 1, 2024. As part of a three-year transition period, the agency identified 266 musculoskeletal services, such as hip and knee arthroplasty and spine procedures, for removal in CY 2021. UC Health supports the goal of providing more choice to patients and providers regarding the care setting. **However, we are concerned about the potential for unintended consequences associated with eliminating the IPO list, and the proposed three-year time frame for removal.**

Moreover, the proposed 3-year timeline to eliminate the IPO list is inadequate to fully assess the impact of moving certain procedures to the outpatient setting. In the past, CMS has solicited stakeholder feedback for the removal of procedures from the IPO list. As technology changes to allow for more procedures to be performed in the outpatient setting, the IPO list has been modified to accommodate these changes. We believe this process should continue. **Therefore, we urge CMS to delay finalizing the elimination of the IPO list and solicit stakeholder feedback to comprehensively evaluate which procedures should remain in the inpatient setting given concerns about beneficiary safety and outcomes, and evolving standards of care.**

We thank CMS for considering our comments. Please refer any questions you may have to UC system's Senior Advisor Georgette Lewis (georgette.lewis@ucop.edu /(510)-587-6227).

Sincerely,

Carrie Byington

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