



A Passionate Voice for Compassionate Care

September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS-1678-P

Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Ms. Verma:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (82 Federal Register 33558 – 33724, July 20, 2017).

We appreciate your staff's ongoing efforts to administer and improve the payment systems for outpatient hospital and ambulatory surgical services, especially considering the agency's many competing demands and limited resources. CHA offers the following comments on the proposed rule.

- **Alternative Payment Methodology for Drugs Purchased under the 340B Drug Discount Program**

CMS proposes to drastically reduce Medicare Part B payment to hospitals participating in the 340B drug discount program. Currently, CMS pays all hospitals for separately payable drugs under the OPPS (excluding drugs on pass-through status and vaccines) at the average sales price (ASP) +6 percent, regardless of the price at which the hospitals acquire the drugs. CMS now proposes to cut that payment to ASP *minus* 22.5 percent, a reduction of nearly 27 percent. CHA strongly opposes CMS' proposal and urges CMS to withdraw it. CMS lacks authority to make this change, which if implemented would undermine the very purpose of the 340B and cause harm to 340B hospitals, to the communities and patients those hospitals serve, and to Medicare beneficiaries.

The 340B Drug Discount Program allows hospitals serving low-income and vulnerable populations to purchase certain “covered outpatient drugs” at discounted prices from drug manufacturers. As CMS notes in its proposed rule, “the statutory intent of the 340B program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and provide care that is more comprehensive.” To be eligible, a hospital must have with a disproportionate share hospital (DSH) percentage that is 11.75 percent or higher (8.0 percent or higher for rural referral centers and sole community hospitals) and must be owned by a state or local government or be a non-profit hospital under contract with a State or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid. Thus, as CMS’ proposed rule makes clear, the 340B program is specifically designed to give resources to non-profit and government hospitals that serve high proportions of low-income patients to provide services to patients that are otherwise not being served by public health insurance programs.

CMS lacks the authority under the Medicare statute to implement this proposal. Payment for separately payable drugs under the OPDS is governed by paragraph (14) of section 1833(t) of the Act (42 U.S.C. Section 1395l(t)). For years subsequent to 2005, paragraph (14) (A)(iii) provides two alternative methodologies (under subclauses (I) and (II) shown below) for the calculation of payment amounts for separately payable drugs. Payment must be equal:

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group [(as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)], as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

CMS has set payment rates using the method in subclause (II) since 2012. Unlike the methodology under subclause (I), subclause (II) does not give the Secretary authority to vary payment rates by hospital group. By attempting to establish a separate rate for a specific hospital group, those participating in the 340B program, CMS has exceeded its statutory authority. Furthermore, the magnitude of the payment change proposed by CMS contravenes the intent of the statute. Clearly what is contemplated by the statute is a reasonable year to year adjustment of payment to reflect normal fluctuations in the price of drugs. CMS’ proposal would subject 340B hospitals to what it estimates to be a \$900 million cut (other estimates project larger cuts), with potentially devastating effects on some hospitals. **What CMS has proposed goes beyond a reasonable annual adjustment and amounts to a significant change in policy, one it is not authorized to make.**

CMS' proposal contravenes and undermines the 340B statute. In the proposed rule, CMS cites studies by the Medicare Payment Advisory Commission, the Department of Health and Human Services Office of the Inspector General and the General Accountability Office to demonstrate that 340B eligible hospitals acquire drugs for less than the ASP+6 percent price at which Medicare pays for the drug. This result is to be expected because the purpose of the 340B drug discount program is to provide eligible hospitals with lower cost access to drugs so those hospitals can use resources that would otherwise be spent purchasing drugs to provide services to low-income patients and communities. The difference between the discounted price and the reimbursement amount is the very means by which Congress intended to provide those hospitals with additional needed resources, “to maximize scarce Federal resources as much as possible, reaching more eligible patients, and provide care that is more comprehensive.”

CHA questions whether it is CMS' prerogative to make this policy proposal. CMS' proposal disregards the Congressional intent of the 340B program by taking drug discounts intended for specified eligible hospitals that serve low-income patients and giving them to all hospitals paid under the OPSS. This occurs because CMS proposes to make the savings associated with its 340B proposal budget neutral through an upward adjustment under the OPSS to payments for all hospitals. CMS lacks authority to redirect funds Congress clearly intended for eligible 340B hospitals to hospitals that do not participate in the 340B program. Congress most recently expanded the 340B program in 2010 as part of the Affordable Care Act. It did not then, nor has it ever, sought to reduce or eliminate the surpluses generated under the 340B program. To the contrary, Congress has over the years increased the types of entities that may participate in the program and use those surpluses to serve their communities. **The effect of the proposed reimbursement rate constitutes a fundamental change to the 340B program, a policy change only Congress, not CMS, has the authority to make.**

CMS' proposal would undermine the purpose of the 340B statute by taking away many resources from 340B hospitals and those they serve. Savings generated by the 340B program allow hospitals to provide many types of assistance to low-income patients and communities, such as providing access to free or reduced priced drugs for those who cannot afford their prescriptions; clinical pharmacy services; funding for services such as obstetrics, psychiatry, diabetes education, and oncology; and establishing outpatient services to increase access.

Many vulnerable communities are served by 340B hospitals. Research by Dobson Davanzo & Associates has shown that 340B DSH hospitals are more likely to treat low-income and underserved patients than other providers. Hospitals in the 340B program serve significantly more Medicaid and low-income Medicare patients and provide more uncompensated care than do non-340B hospitals. They are also more likely to serve disabled Medicare patients, beneficiaries who are dually eligible for Medicaid, and patients from a racial or ethnic minority. They are also more likely to treat low-income Medicare cancer drug recipients than non-340B hospitals. (Financial Challenges Faced by 340B Disproportionate Share Hospitals in Treating Low-Income Patients, August 4, 2017, http://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf).

If CMS proceeds to finalize its proposal, 340B eligible hospitals will have fewer resources to provide services to low income and rural communities than they do today. For some hospitals, loss of these resources could challenge their very existence. In the end, it is not 340B hospitals that will be most harmed by CMS' proposal, but the communities they serve.

The proposal would not benefit Medicare beneficiaries. CMS asserts that reducing payments to 340B hospitals will also result in savings for Medicare beneficiaries through reduced copayments. That outcome is very unlikely, however. First, MedPAC reported in its June 2016 Data Book that 86 percent of Medicare beneficiaries have their copayments covered through supplemental coverage. Second, CMS' proposes to make this change budget neutral means reimbursement to hospitals for other Medicaid services would increase, with a corresponding increase in beneficiary copayment.

CMS' proposed modifier for non-340B drugs would be unduly burdensome. CMS proposes to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B program. In order to distinguish 340B drugs from non-340B drugs, CMS intends to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B program. CMS has indicated that additional details regarding this modifier will be in the final rule and sub-regulatory guidance, including guidance related to billing for dually eligible beneficiaries for whom covered entities do not receive a discount under the 340B program. CHA is concerned that this new modifier will impose administrative burdens and be expensive and very difficult to implement. We also note it runs contrary to CMS' stated pledge to reduce regulatory burdens under the Medicare program.

CMS's approach conflicts with how a number of state Medicaid agencies administer their Medicaid rebate programs to prevent duplicate discounts on 340B drugs. To accurately collect rebates, some state Medicaid agencies identify 340B drugs with a modifier or their National Drug Code (NDC) code so that if the modifier or NDC code is not on the claim, the drug is eligible for a Medicaid rebate. CMS's proposal is the exact opposite, and it will add confusion and complexity to an already complicated system.

Implementing CMS's proposed modifier accurately will be difficulty and expensive. Some hospitals would have to report the modifier manually, resulting in an increase in workload. Upgrading or purchasing appropriate software would be costly. In addition, the modifier would have to be added to the claim at the time service is rendered or retroactively applied, delaying the submission of the claim. This would pose challenges in mixed-use areas, such as emergency departments, catheterization laboratories and pharmacies, where both 340B eligible patients and non-340B patients are served.

For these reasons, and especially because of the possible harm to individuals and communities in need, CHA strongly opposes CMS' proposal and urges CMS to withdraw it.

- **Proposed Changes to the Inpatient Only (IPO) List**

CMS proposes to remove total knee arthroplasty (TKA) from the IPO list on the basis that it believes that TKA meets criteria 1, 2 and 4 of the below criteria that are used to determine whether a procedure should be removed from the IPO list:

The criteria for a procedure to be removed from the IPO list include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

The proposed rule does not provide the evidence upon which CMS concludes that criteria 1, 2 and 4 are met but requests comments on whether TKA meets any of the above criteria (not all five need to be met for a procedure to be removed from the IPO list). Absent the evidence that CMS used to conclude the TKA meets several of the criteria to be removed from the IPO list, CHA is unable to make an informed comment on CMS' proposal. Nevertheless, it seems logical and evident from the discussion in the proposed rule that TKA would only be safely and appropriately performed on an outpatient basis very selectively for younger patients with strong post-surgical home support and no underlying conditions that would complicate the surgery. CHA believes Medicare patients (who are over 65 years of age, disabled for more than 2 years or have end-stage renal disease) are unlikely to meet these conditions. For these reasons, **CHA opposes CMS' proposal to remove TKA from the IPO list.** Nevertheless, if CMS proceeds to finalizing this rule, CHA supports prohibiting Recovery Audit Contractors from reviewing TKA for patient status determinations and CMS' statement that the determination of whether to perform TKA on inpatient or outpatient basis rests solely with the physician and the patient based on the needs of the patient.

We further note that CMS' proposal does not address how its proposal to remove TKA from the IPO list will affect participants in the Comprehensive Care for Joint Replacement (CJR) model. While CMS recently proposed to reduce mandatory participation in CJR from 67 to 34 metropolitan statistical areas and allow voluntary participation in the remaining 33 areas, remaining participants need to know how target prices and performance will be measured if Medicare finalizes its policy to allow TKA to be paid in the hospital outpatient department or ambulatory surgical centers (where CMS has not, yet, proposed to make TKA payable).

CMS does not make a proposal but requests comments on whether to remove partial and total hip replacement from the IPO list. CHA reiterates that our earlier comments for TKA are equally, if not more, applicable for partial and total hip replacement. It seems unlikely that Medicare patients are likely to be good candidates for outpatient hip replacement surgery given their age and likely presence of potential complicating conditions. Once again, we urge CMS to use all deliberate caution and ensure that the safety of Medicare beneficiaries is given the highest priority in deciding whether to remove these procedures from the inpatient only list.

- **Enforcement of the Direct Supervision Rules**

In the 2009 OPSS final rule, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospital outpatient departments. In the 2010 OPSS final rule, CMS clarified that direct supervision of therapeutic services applies to CAHs as well as hospitals. For most of the period between March 15, 2010 through December 31, 2016, the direct supervision requirements were subject to an enforcement moratorium either by statute or CMS instruction for CAHs and rural hospitals under 100 beds (since January 1, 2011 for small rural hospitals). CMS proposes to reinstate the nonenforcement of the direct supervision requirements for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for 2018 and 2019.

CHA supports CMS' proposal to reinstate nonenforcement for CAHs and small rural hospitals in 2018 and 2019. However, we urge CMS to apply nonenforcement to 2017 as well and to make the non-enforcement instruction permanent for CAHs and small rural hospitals having 100 or fewer beds because of the difficulties that these facilities have finding sufficient staff to furnish direct supervision. The non-enforcement of the direct supervision rules in CAHs and small rural hospitals with 100 or fewer beds has been almost continuous since 2010, during which time CMS indicates it is not aware of any quality of care complaints from beneficiaries or providers relating to general physician supervision as compared to direct physician supervision for outpatient hospital therapeutic services. CHA believes the proposed rule provides a sufficient basis for CAHs and small rural hospitals with 100 or fewer beds not to be subject to the direct supervision rules.

- **Accounting for Social Risk Factors in the Hospital Outpatient Quality Reporting Program**

CHA appreciates the request for comment on accounting for social risk factors in the Hospital Outpatient Quality Reporting (OQR) Program. All hospitals should be held to high standards of quality for all patients. However, the known links between social risk factors and poor outcomes means that providers serving a high percentage of low-income or otherwise socially challenged patients can be disadvantaged if publicly reported measures do not reflect appropriate adjustments for social risk factors. For this reason, CHA has long urged that quality outcome measures be risk-adjusted for sociodemographic factors such as income, education, race,

homelessness and language proficiency, which have been shown to have a significant relationship to health outcomes. In the context of the OQR Program risk adjustment should be evaluated for measures like OP-36, which assesses hospital visit rates after outpatient surgery.

In its 2014 report the National Quality Forum (NQF) Risk Adjustment Expert Panel recommended that performance accountability programs should include risk adjustment for those sociodemographic factors for which there is a conceptual relationship with outcomes or processes of care and empirical evidence of such an effect, for reasons unrelated to quality of care. As noted by the Assistant Secretary for Planning and Evaluation (ASPE) in its December 2016 report, social risk factors and patient safety events are related, and social risk factors may be a proxy for medical complexity that is not accounted for in performance measures. In addition, more could be done to use performance measurement systems to identify and eliminate health disparities. Enhanced data collection on social risk factors, along with improved statistical techniques as recommended by the ASPE, would allow better measurement of performance and outcomes with respect to individuals with social risk factors.

Finally, CHA generally believes that quality reporting measures should be consistent across providers and programs whenever possible, and that principle should also extend to risk adjustment. Whatever approaches are adopted to account for social risk factors should be aligned for measures and quality reporting programs across sites of care.

- **Changes to OQR Program Measures**

CHA supports the proposed removal of six measures from the OQR Program: OP-21: Median Time to Pain Management for Long Bone Fracture, OP-26: Hospital Outpatient Volume Data, OP-1: Median Time to Fibrinolysis, OP-4: Aspirin at Arrival, OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP-25: Safe Surgery Checklist Use. We agree that OQR Program measures that are topped out, duplicative or for which there is no clear benefit to public reporting do not have value and should be excluded from the program.

In addition, **CHA supports the delay in the implementation of the Outpatient and Ambulatory Services Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) in the OQR Program.** Given the resources that hospitals must invest in fielding and reporting this survey measure, we agree it is prudent to wait until CMS is certain that the measure itself and the operational aspects around reporting these surveys have been fully vetted. We are pleased that as part of this process CMS will consider shortening the survey.

CHA appreciates that CMS expects to reduce the hospital reporting burden with the potential future addition of an electronic clinical quality measure (eCQM) version of the existing chart abstracted measure OP-2: Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival. However, hospitals continue to face challenges with eCQM reporting for purposes of the inpatient quality reporting and the Medicare Electronic Health Record Incentive

Ms. Seema Verma
September 11, 2017
Page 8 of 8

Program. CMS recognized these problems when it chose not to finalize its proposal to increase the number of eCQMs required for those programs in the FY 2018 IPPS/LTCH final rule. **Until ongoing issues with vendors and CMS systems are fully resolved, CMS should not add any eCQMs as mandatory measures to the OQR Program.**

In closing, thank you for the opportunity to share these comments on the proposed 2018 OPSS rule. We look forward to working with you on these and other issues that continue to challenge and strengthen the nation's hospitals. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

A handwritten signature in black ink that reads "Michael Rodgers". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Michael Rodgers
Senior Vice President
Public Policy and Advocacy