



A Passionate Voice for Compassionate Care

September 24, 2018

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-1695-P

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 on the calendar year (CY) 2019 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment rates. This proposed rule also includes provisions on quality reporting and requests for information on promoting interoperability and electronic health care information, price transparency and the competitive acquisition program for Part B drugs and biologicals as part of an Innovation Center Model. 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.

- **Non-opioid Pain Management**

CMS policy does not pay separately for drugs that function as supplies in a procedure performed in the hospital outpatient department. For instance, the proposed rule provides the example of Exparel^(R); an analgesic drug furnished as part of a surgical procedure to control post-surgical pain. As Exparel^(R) is administered during a surgical procedure, Medicare pays for the product as part of its OPPS payment and not separately as it would for a prescription drug furnished post-operatively.

The proposed rule explores whether CMS' policy of not paying separately for non-opioid drugs or devices contributes to less use of alternatives to opioids and, as a consequence, more use of opioids. CMS concludes that utilization of Exparel^(R) has increased in the outpatient department despite packaged payment. However, CMS does not make the same finding in the ASC and therefore, proposes to pay separately for non-opioid treatment alternatives in the ASC setting but not the hospital outpatient department.

CHA supports CMS' goal of establishing policies that will treat and control pain using non-opioid alternatives. To this end, CHA believes **CMS should have consistent policies between the ASC and outpatient department settings by making separate payment for non-opioid treatment alternatives under both the OPPI and in the ASC payment systems. While lessening dependence on opioids is a well-intentioned goal, CHA believes that CMS should be careful to avoid unintended consequence of making it harder for those patients with genuine need for opioids to access them.**

- **Paying Wholesale Acquisition Cost (WAC) + 3 Percent in place of WAC + 6 Percent**

Separately payable Part B drugs furnished in the hospital outpatient department are generally paid using average sales price (ASP) + 6 percent. WAC + 6 percent is used when ASP is unavailable (generally during the first two quarters after a drug comes on the market) or where WAC + 6 percent pays less than ASP + 6 percent. WAC-based pricing is also used by Medicare Administrative Contractors (MAC) when CMS does not determine a national price for a Part B drug. CMS is proposing to change the WAC add-on from 6 percent to 3 percent. **CHA is concerned that paying less for new drugs when they first come on the market may discourage hospitals from using the latest and most innovative new drugs because of payment concerns and urges CMS not to finalize this proposal.**

- **Services Furnished in Off-Campus Provider-Based Departments**

Section 603 of the Bipartisan Budget Act (BBA) of 2015 amends section 1833(t) of the Act, which governs how Medicare makes payment under the hospital Outpatient Prospective Payment System (OPPS). Except for dedicated emergency departments and other limited exceptions, section 603 precludes off-campus provider-based departments (PBDs) that opened after November 2, 2015 ("non-excepted 603 off-campus PBDs") from being paid under the OPPS. Non-excepted 603 off-campus PBDs are paid using another "applicable payment system" under Medicare Part B. Congress excepted from this new policy off-campus PBDs that existed prior to that date ("excepted 603 off-campus PBDs"), and they are to continue to be paid under the OPPS.

In the 2017 OPPS interim final rule with comment (81 FR 79720 through 79729), CMS adopted the physician fee schedule (PFS) as the "applicable payment system" for CY 2017 and set the payment rate at 50 percent of what would have been paid under the OPPS. The final PFS rule for CY 2018 reduced the payment to 40 percent of the OPPS rate. CMS' proposed rule for the CY 2019 PFS would continue that policy.

Services Furnished in Off-Campus Emergency Departments

Under current policy, CMS requires excepted 603 off-campus PBDs to report modifier "PO" on claims. Non-excepted 603 off-campus PBDs are required to report modifier "PN" on claims. In the CY 2019 OPPS rule, CMS indicates that effective January 1, 2019, it will require a new modifier to be reported with every claim line for outpatient hospital services furnished in off-campus provider-

based emergency departments. The modifier would be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals would not have to report this modifier. CMS is using the CY 2019 OPSS rule to announce its implementation of the new modifier through a sub-regulatory process.

CHA is concerned that requiring a new modifier on hospital outpatient claims for services furnished in off-campus emergency departments imposes an additional administrative burden on hospitals. Unlike modifier “PN” which is needed to apply the BBA 2015 section 603 payment policy, neither modifier “PO” or the new modifier being adopted by CMS are necessary to process and pay claims. Further we note that section 603 of the BBA 2015 explicitly excepts services furnished in dedicated emergency departments from its provisions. **CHA urges CMS to reconsider this policy as it appears to be inconsistent with its “Patients Over Paperwork” initiative which is intended to reduce administrative burdens on providers in order to allow them to spend more time serving patients.**

Reducing Medicare Payment for a Clinic Visit

In the CY 2019 OPSS proposed rule, CMS proposes to apply the PFS relativity adjuster of 0.4 (40 percent) to the full OPSS payment of \$116 to pay \$46 for an outpatient clinic visit in an excepted 603 off-campus PBD. CMS cites section 1833(t)(2)(F) of the Social Security Act (the Act) as its authority for reducing the OPSS payment for a clinic visit in an excepted 603 off-campus PBD by 60 percent. Section 1833(t)(2)(F) of the Act provides the Secretary with authority “develop a method for controlling unnecessary increases in the volume of covered OPD services.” CMS indicates that there has been an unnecessary increase in OPD utilization in recent years justifying this payment reduction.

CHA opposes CMS’ proposed payment reduction of 60 percent to an excepted OPSS clinic visit for several reasons. CMS lacks statutory authority for this proposed action. Section 603 specifically excepts off-campus PBDs that were billing under the OPSS prior to November 2, 2015 from its provisions. CMS is explicitly proposing to apply the same payment reduction to an excepted 603 off-campus PBD that it applies to a non-excepted 603 off-campus PBD inconsistent with the statutory exception provided by section 603.

Nor is the proposed policy consistent with CMS’ authority under section 1833(t)(2)(F) of the Act’s to establish “a method” for controlling increases in the volume of covered OPD services. CMS’ proposal is a payment reduction, not a “method” for controlling utilization. CHA further notes that CMS proposes to exempt the payment reduction from the budget neutrality requirements under the statute on the basis that the change is not an “adjustment” yet CMS arrives at the 40 percent payment amount by applying the “PFS relativity adjuster” to the full OPSS payment rate.¹

¹ See 83 FR page 37142. In the 3rd column, CMS argues that the proposed payment changes under section 1833(t)(2)(F) of the Act are not “adjustments.” However, earlier in that same column CMS states that “for a discussion of the PFS relativity adjuster that will now be used to pay for all outpatient clinic visits...”

In addition, while CMS identifies increased utilization of OPSS services it has not identified those services as unnecessary. Rather, CMS believes these services do not need to be furnished in the hospital outpatient department. The implication of CMS' proposed rule is that the utilization increases it observed were for services more appropriately furnished in a physician's office than a hospital outpatient department. Without analyzing the clinical circumstances of these cases, CMS is not in a position to determine whether the cases were of sufficient severity and complexity that a visit in the outpatient department was unwarranted compared to a physician's office. CHS believes the patient's clinician is in the best position to determine the appropriate site of care for the patient. CMS has also neglected to address other Medicare payment policies and outside factors that have contributed to increased use of outpatient services.

For the reasons provided above, CHA respectfully urges CMS not to finalize its proposal to reduce payment for a clinic visit in an excepted 603 off-campus PBD to 40 percent of the OPSS rate.

Limitations on new/additional services at excepted off campus PBDs

In the CY 2019 OPSS proposed rule, CMS proposes to limit expansion of services in excepted 603 off-campus PBDs effective January 1, 2019. Under CMS' proposal, an excepted 603 off-campus department would be paid under the OPSS for a new item or service from a clinical family of services from which it furnished a service during the November 2, 2014 to November 2, 2015 baseline period. The excepted 603 off-campus department would be paid at the PFS adjusted OPSS rate for items or services from any clinical family of services from which it did not furnish an item or service during the baseline period.

CHA opposes CMS' proposal. First, CMS does not provide a statutory basis under which it has authority to limit expansion of services in an excepted 603 off-campus PBD. As explained earlier, section 603 excepts off-campus PBDs that were billing under the OPSS prior to November 2, 2015 from its provisions. CHA believes that the proposed policies on expansion are inconsistent with the plain meaning of the statute, the better reading of which is that excepted 603 off-campus PBDs should be completely outside of the reach of section 603. CMS' proposal will apply section 603's provisions to off-campus PBDs that were billing under the OPSS as of November 2, 2015 despite the provisions explicitly excepting these off-campus PBDs. **CHA requests that CMS not finalize its proposal, which is beyond the authority of CMS to make.**

Second, CMS' proposal imposes significant administrative burden on hospitals. To comply with this proposed policy, excepted off-campus PBDs must ascertain the clinical families of services from which they furnished services during the baseline period. If a service was furnished outside of that clinical family of services from the base period, the service would be reported with modifier "PN" and paid at the special PFS rate equal to 40 percent of the OPSS. CMS proposed policy presents a number of administrative difficulties. For instance, clinical families have changed between the baseline period and the current year making it impossible to know whether a given

service is or is not subject to the expansion limitation. Given these and other administrative difficulties that require further guidance from CMS, **CHA requests CMS not finalize its proposal.**

Finally, CHA hospitals provide services to low income and rural communities. Payment rates under the existing provisions of section 603 are already affecting access to needed services by lessening the hospital's ability to move into these communities when physicians are leaving their practices. Reducing payment to hospitals further can only lessen access to needed services in these vulnerable communities. CMS is not adequately taking into account the role off-campus PBDs play in the communities they serve as a crucial and often only point of access for health care services. Hospitals have to be able to meet the changing medical needs of their communities; they must also be able to adapt to changes in technology or the best practice guidelines. The ability of physicians and facilities to serve their communities will be severely limited if decisions about what services they can afford to furnish are established in regulation. CHA is concerned that as proposed this policy would limit patient access to quality care in many areas and would result in the inefficient increase in emergency department visits, including at main providers, when an off-campus outpatient department would be far better suited to efficiently meet those health care needs. **CHA opposes this proposal and urges CMS not to finalize a limitation in the OPSS-reimbursable services that excepted off-campus PBDs may provide.**

Expanding the 340B Policy to Non-Excepted 603 Departments

CMS finalized and implemented for the CY 2018 OPSS its proposal to drastically reduce Medicare Part B payment to hospitals participating in the 340B drug discount program. Whereas CMS pays all hospitals for separately payable drugs under the OPSS (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, it now reimburses for 340B drugs at ASP - 22.5 percent, a reduction of nearly 27 percent. As detailed in our comment letter to the OPSS/ASC proposed rule for CY 2018 (CMS-1678-P), CHA believes that CMS exceeded its statutory authority in establishing this policy for off-campus provider-based departments (PBDs) of a hospital that are excepted from the application of section 603 of the BBA 2015. CMS' policy also directly conflicts with the policy of the 340B program and undermines the 340B statute, which is intended 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.

CMS's current proposal to extend this payment policy of ASP-22.5% for drugs and biologicals furnished by non-excepted off-campus PBDs of hospitals participating in the 340B program also exceeds its statutory authority. Section 1833(t)(21)(C) of the Act (as added by section 603) requires the agency to pay for applicable items and services (including drugs and biologicals) furnished by non-excepted off-campus PBDs under an "applicable payment system" under Part B of the Medicare program (other than the OPSS). The applicable payment system under Part B for drugs and biologicals that are not paid at cost or not paid under a prospective payment system is section 1842(o)(1) of the Act. Specifically, section 1842(o)(1)(C) of the Act requires that the payment for drugs and biologicals is to be made under one of several payment

methodologies, and the ASP payment methodology under section 1847A applies to the drugs and biologicals furnished by section 603 non-excepted off-campus PBDs.

These provisions of the statute (viz. section 1842(o)(1) and section 1847A of the Act) have long governed payment for the vast majority of Part B drugs and biologicals not paid under the OPPS. Nothing in the language of section 1833(t)(21)(C) grants CMS the authority to establish a new Part B payment methodology or provides any authority to modify the otherwise applicable payment rate of ASP+6 percent required under section 1847A.

We stress again that these policies undermine the purpose and language of the 340B program and hamper the ability of 340B hospitals to serve low-income and rural communities. Savings generated by the 340B program allow hospitals to provide services such as free and low-cost clinics; infusion, dialysis and other needed services in remote or low-income areas; programs that provide low-cost or free drugs for those who cannot afford their prescriptions; and critical hospital services that operate at a loss. **CHA urges CMS not to finalize its proposal to expand the current and flawed 340B policy to non-excepted 603 departments.**

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

CHA has ongoing concerns about the impact of health disparities and 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. The result of known links between social risk factors and poor outcomes is that providers serving a high percentage of disadvantaged patients can be subject to unnecessary payment reductions if appropriate adjustments for social risk factors are not made in performance-based payment incentive programs.

We are pleased that CMS reports continuing efforts to further consider accounting for social risk factors in the OQR Program, including input from a Technical Expert Panel considering stratification of IQR Program measures. Importantly, as noted in the proposed rule, the National Quality Forum (NQF) has extended its trial examining social risk factors in outcome measures.

CHA continues to believe that 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 Assistant Secretary for Planning and Evaluation, would allow better measurement of performance and outcomes with respect to individuals with social risk factors.

- **Hospital Outpatient Quality Reporting Program**

CHA supports the proposed addition of an eighth factor for consideration in removing measures from the OQR Program and the proposed removal of ten measures. Proposed Factor

8, which has now been adopted for the Inpatient Quality Reporting Program and others, would allow CMS to consider removal of a measure when the costs associated with the measure outweigh the benefits of its continued use in the program. As we suggested with respect to the use of this removal factor in IQR Program, consideration of costs should include not just the data submission requirements but all the resources required for providers to perform well on the measure, such as monitoring performance and developing strategies for performance improvement. We agree that the proposed new removal factor provides the opportunity for CMS to streamline measures to meet the goals of improving patient outcomes while minimizing provider burden.

With respect to the ten measures proposed for removal, we agree with the rationales offered by CMS, which are consistent with the goal of streamlining the measure set to focus on those that will best promote improved patient outcomes. The ten measures include a voluntary measure on cataract function originally designed for clinicians along with four others that are proposed for removal based on the proposed cost and benefit factor; a mammography measure that reflects clinical guidelines that are out of date; two measures for which hospital performance is topped out; and two measures that effectively are surveys of hospital use of health information technology.

- **Inpatient Quality Reporting Program (IQR) HCAHPS Pain Questions**

CMS proposes to remove the three questions about pain communication from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with 2022 discharges (for FY 2024 payment). CHA supported both of CMS' recent actions concerning HCAHPS pain questions: the removal of the three-question HCAHPS survey Pain Management dimension from the hospital VBP Program in the CY 2017 final OPPI rule and the revision of the HCAHPS pain questions in the final CY 2018 payment rule. CMS' actions were motivated by confusion about the intent of these questions and, in the context of the public health crisis surrounding the opioid overdose epidemic, the desire to avoid even the possibility that the questions could lead to over-prescription of opioids.

CHA appreciates CMS' taking great care to avoid creating incentives that favor the use of powerful prescription drugs such as opioids in pain management. When a measure is believed to have significant unintended consequences, it is prudent that its use be discontinued until concerns can be examined and tested. At the same time, understanding more about pain management communication and a patient's perception of it in relation to their care is an important part of patient experience and the healing process. Effective pain management is an essential element of patient well-being and a key element in the provision of palliative care services to patients and families facing serious illness. The Catholic health ministry is strongly committed to providing patients with excellent palliative care services, which focus on providing relief from the symptoms, pain and stress of a serious illness. **While CHA supports the proposal to discontinue use of the questions for 2022 discharges, we recommend CMS continue to work with the National Quality Forum (NQF), the Measure Applications Partnership (MAP) and stakeholders to study the questions and consider whether and how to gather patient**

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information about pain management. We suggest that experts in pain management and palliative care be part of the dialogue as CMS considers next steps.

- **Request for Information on Promoting Electronic Interoperability**

CMS seeks comment on whether conditions of participation for hospitals and other facilities should be modified to advance electronic exchange of health information in support of care transitions.

While CHA supports to goal of promoting electronic interoperability, we do not believe that the conditions of participation are an appropriate tool for advancing this goal. Hospitals already have a very strong financial incentive to participate in health data exchange under the Medicare and Medicaid Promoting Interoperability Program: A hospital that fails to meet the requirements for meaningful use of CEHRT, which include healthcare information exchange, loses three quarters of the market basket update factor under the IPPS. Smaller, low-volume facilities that may be lagging in meeting meaningful use requirements may be forced to close if interoperability becomes a condition of participation in the Medicare program. That outcome would not be in the best interest of Medicare beneficiaries and would not result in greater interoperability.

In closing, thank you for the opportunity to share these comments on the proposed 2018 OPPI 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,



Michael Rodgers
Senior Vice President
Public Policy and Advocacy