



A Passionate Voice for Compassionate Care

September 27, 2019

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

Submitted electronically to: <http://www.regulations.gov>

REF: CMS-1717-P

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospital; Proposed Rule, 84 Fed. Reg. 39398 (August 9, 2019)

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) 2020 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment rates. This proposed rule includes provisions on price transparency, payment for part B drugs acquired under the 340B program, payment for outpatient clinic visits, supervision of outpatient therapeutic services, allowing payment for hip replacements in the outpatient department, adding knee replacement to the ASC list among other provisions. 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.

- **Price Transparency**

In the FY 2019 IPPS rule, CMS revised its implementation of section 2718(e) of the Public Health Service (PHS) Act to require that hospitals make public their standard charges for all items and services in a machine-readable format (83 FR 41686). In the CY 2020 OPPS rule, CMS is proposing to further require that hospitals make public:

- Gross charges and payer-specific negotiated charges for all items and services; and
- Gross charges and payer-specific negotiated charges for 300 shoppable services; hospitals could choose among a list of up to 70 shoppable services provided by CMS and additional 230 or more that the hospital would self-select. For shoppable services, hospitals would be required to post the required information on their websites in a consumer-friendly manner.

In addition, the rule proposes a number of complex requirements related to the electronic format under which the information would be posted, its location on hospital websites, accessibility, and the frequency of updates among other requirements.

CHA has significant concerns about this proposal including the usefulness of the required information to patients, the legality of the policy, and the potential conflicts with other federal policies. In addition, these requirements will be highly burdensome to hospitals and divert needed resources away from informing patients of their out-of-pocket costs for a hospital stay. **CHA opposes this proposal because of these concerns and requests that CMS withdraw it.**

Patients are most concerned with the amounts that they will be paying out-of-pocket when they need health care services. They are not interested in the negotiated rate between hospitals and private insurers, nor is that information useful to them. Hospitals spend considerable time and effort working to accurately inform patients about how much a hospital stay will cost them. These efforts give patients a reasonable expectation of their planned out-of-pocket expenses based on their insurance plan and minimize the potential for surprise bills. Patients should also be able to obtain information on their out-of-pocket costs from their health plans.

CMS' proposal will impose significant burdens on hospitals by requiring the posting of dozens, if not hundreds, of private payer rates, for thousands of different services. Given the amount of information hospitals will be required to collect and post, the effort involved will far exceed the 12-hour estimate CMS provides in the proposed rule. The proposed information CMS is requiring hospitals to report will prove to be no more useful than that which CMS already requires hospitals to report. Shortly after the current requirements went into effect on January 1, 2019, there were a number of media articles that found charge information being reported by hospitals to be confusing and unhelpful to health care consumers. A recent article in *Health*

Affairs described the information as “indecipherable to the lay consumer.”¹ CMS’ proposal will not only add to the confusion, it will further detract from ongoing efforts to inform patients of their expected out-of-pocket costs for a hospital stay.

Section 2718(e) of the PHS Act requires that hospitals make public “a list of the hospital’s standard charges for items and services.” Longstanding Medicare policy defines charges as

[R]egular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.²

A standard charge, by definition, is “regularly and widely used, available or supplied” and “substantially uniform.”³ “Payer-specific negotiated” charges are not standard charges as they not uniform, regular and widely used. Rather, a payer-specific negotiated charge may be different for each payer and reflect the specific outcome of negotiations between the hospital and the payer. CMS’ proposal is inconsistent with section 2718(e), which does not provide legal authority for CMS’ proposed action.

We further understand that the Department of Justice (DOJ) and the Federal Trade Commission (FTC) have antitrust concerns with revealing proprietary confidential information⁴ and also note CMS is requiring hospitals to make information public that the statute prohibits CMS itself from disclosing.⁵ Conflicts with DOJ and FTC policy and other statutory provisions are additional reasons that CHA recommends CMS reconsider this proposal.

CHA and its members are committed to making sure everyone has access to affordable health care and believe that patients should know what their out-of-pocket costs will be when making health care decisions. **CMS should not finalize this proposal because it will not serve that end, is without legal authority, and will impose unreasonable burdens on hospitals. CMS should instead work with health plans, patients, providers and other stakeholders to find reasonable and effective ways to get patients information they need and can use.**

¹James C. Capretta, “The New Hospital Price Disclosure Rule Is Important, But Only A First Step,” *Health Affairs*, August 26, 2019.

² Provider Reimbursement Manual, No 15-1, Chapter. 22, § 2202.4.

³ <https://www.merriam-webster.com/dictionary/standard>.

⁴ <https://www.justice.gov/atr/page/file/1197731/download>; page 43.

⁵ Section 1834A(a)(10) of the Act explicitly prohibits the Secretary from disclosing private payer rates reported by “applicable laboratories” which effective January 1, 2019 includes hospital outreach laboratories that receive a referred specimen.

- **340B Payment Policies**

In the 2018 OPPS rule, CMS adopted a policy to pay separately payable Part B drugs in the hospital outpatient department acquired under the 340B program at average sales price (ASP)-22.5 percent in place of ASP+6 percent. CHA objected to CMS' policy at that time on legal and policy grounds. In our public comments, CHA stated that CMS lacks authority to make this change, which has undermined the very purpose of the 340B program and caused harm to 340B hospitals, to the communities and patients those hospitals serve, and to Medicare beneficiaries. Despite objections from CHA and others, CMS decided to finalize its policy for 2018 which it later continued for 2019 and now proposes to extend into 2020.

On December 27, 2018, the United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018.⁶ On May 6, 2019, the District Court ruled that the rate reduction for 2019 also exceeded the Secretary's authority. The Secretary is currently appealing the District Court's decision.

In the 2020 OPPS rule, CMS both proposes to extend its 340B payment policy of ASP-22.5 percent into 2020 and requests public input on how to craft a remedy were the Circuit Court to uphold the District Court's decision on appeal. **CHA continues to object to the reduction in reimbursement for 340B drugs and opposes CMS' proposal to extend the payment rate ASP-22.5 percent into 2020, despite the District Court determination that it is unlawful.** While CHA disagrees with CMS concern that remedial action would be complex due to the number of hospitals involved and CMS' contention that budget neutrality requirements must be applied, given its articulated concern prudence would mandate that CMS avoid exacerbating the situation by reverting back to a policy of ASP+6 percent pending the resolution of its appeal.

CMS requests comments on whether ASP+3 percent would be "an appropriate remedial payment amount" both for 2020 and determining the remedy for 2018 and 2019. **CHA does not believe that paying at ASP+3 percent would be appropriate as a matter of law and policy.** As a matter of law, the statutory authority that CMS is using to pay for Part B drugs only allows the agency to default to a payment methodology already existing in statute (ASP+6 percent). CMS does not have the statutory authority to discriminate in payment by paying one group of hospitals at ASP+3 percent and all other hospitals at ASP+6 percent.

As a matter of policy, savings generated by the 340B program allow hospitals to provide many types of assistance to low-income patients and communities, including 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 establish outpatient services to increase access. Given the purpose of the 340B program is to "maximize scarce Federal resources as much as possible, reaching more eligible patients, and provide care

⁶ *AHA v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018).

that is more comprehensive,” CHA believes that CMS should return to paying for Part B drugs acquired under the 340B program at ASP+6 percent.

With respect to a remedy for 2018 and 2019 if the District Court’s decision invalidating payment based on ASP-22.5 percent is upheld, CMS requests comment on whether the additional payment should be made:

1. On a claim-by-claim basis
2. Through an upward adjustment to 340B claims in the future to account for any past underpayments, or
3. Through lump sum payments to each hospital paid at ASP-22.5 percent that are then made budget neutral in a future year through payment reductions to all other services.

CMS requires hospitals to bill for 340B acquired drugs with modifier “JG” on the outpatient claim so that payment can be made at ASP-22.5 percent. Use of modifier “JG” will make it a simple matter for CMS to identify those hospital claims where part B drugs were paid at the reduced ASP-22.5 percent rate. Once the modifier “JG” claims are identified, **CMS could easily determine the difference between payment based on ASP+6 percent and ASP-22.5 percent and provide a lump sum payment to each affected hospital.**

CMS should not recoup past additional payments that resulted from the budget neutrality adjustment applied for the reduction in part B drug payments. There is precedent for making non-budget neutral changes to IPPS payments in response to a judicial decision. 42 CFR section 412.64(L) states:

If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

CMS does not then go back and apply budget neutrality for revisions to the wage index that result from judicial decisions. The additional payments made to hospitals as a result of CMS’ 340B payment policy in 2018 and 2019 were the result of CMS’ own actions. CHA does not believe these hospitals should be penalized for two years of back payments (three years if CMS decides to extend ASP-22.5 percent payment into 2020), the receipt of which was beyond their control and not due to their own action.

Similarly, **CHA believes patients should be held harmless from having to pay additional coinsurance on the higher payments for 340B drugs.** Concerns about not collecting coinsurance are about whether the lack of an expense or a reduced expense illegally serves as an inducement to the beneficiary to use a product or service. As the additional payment for 340B

drugs are for drugs already administered, not collecting coinsurance will not serve as an illegal inducement to the beneficiary.

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

Section 603 of the Bipartisan Budget Act (BBA) of 2015 provides that off-campus provider-based departments (PBDs) that opened after November 2, 2015 (“non-excepted off-campus PBDs”) are no longer paid under the OPPS. They are instead paid using another “applicable payment system” under Medicare Part B. CMS has adopted the physician fee schedule (PFS) as the “applicable payment system” and sets the rate using a PFS relativity adjuster which is applied to the rate that would have been paid under the OPPS. Congress excepted from this new policy off-campus PBDs that existed prior to November 2, 2015 (“excepted off-campus PBDs”), and they are to continue to be paid under the OPPS.

In the CY 2019 OPPS final rule, CMS adopted a policy to apply the PFS relativity adjuster to clinic visits (HCPCS code G0463) in excepted off-campus PBDs in two steps, resulting in payment at 70 percent of the OPPS rate in 2019 and 40 percent of the OPPS rate in 2020. CMS cited section 1833(t)(2)(F) of the Social Security Act (the Act) as its authority for reducing the OPPS payment for a clinic visit in an excepted 603 off-campus PBD. 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 further exempted this payment change from the required budget neutrality requirements that customarily apply to OPPS payment changes. CHA opposed this policy as being inconsistent with the statute.

On September 17, 2019, the United States District Court for the District of Columbia ruled in favor of the plaintiffs and vacated applicable portions of the final rule.⁷ As the District Court has now vacated CMS’ policy, CHA believes that CMS may not continue with its plan to pay for clinic visits in excepted off-campus PBDs at 40 percent of the OPPS rate. The applicable portions of the 2019 rule are no longer effective as a result of the Court’s decision. CMS must, therefore, default to the prior rule which requires CMS to pay for a clinic visit in an excepted off-campus PBD at 100 percent of the OPPS rate. **CHA strongly encourages CMS to restore payment beginning in 2020 for an outpatient clinic visit in an excepted off-campus PBD to 100 percent of the OPPS rate, and to make remedial payments to hospitals for underpayments in 2019.**

As we noted in our comments last year, 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

⁷ *AHA v. Azar* (1:18-cv-02841) (Sept 17, 2019).

only point of access for health care services. **Thus, CHA requests CMS restore payment to the full OPPTS payment amount for policy as well as legal reasons.**

- **Supervision of Outpatient Therapeutic Services**

In the CY 2009 OPPTS rule CMS clarified its policies with respect to supervision of outpatient therapeutic services. With limited exceptions, Medicare requires direct supervision for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals and PBDs of hospitals. There has been either an administrative or statutory enforcement moratorium on the direct supervision rules for CAHs and rural hospitals under 100 beds for nearly all of the period since March 15, 2010 until now.

Stakeholders stated that the enforcement moratorium is needed because small rural hospitals and CAHs have insufficient staff available to furnish direct supervision, particularly for critical specialty services. The non-enforcement instructions have created a two-tiered system of physician supervision requirements. Direct supervision is required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision is required for the same services in CAHs and small rural hospitals with fewer than 100 beds.

CMS is proposing to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct to general supervision for services furnished by all hospitals and CAHs. As it has done in the past, CMS will continue to have the Hospital Outpatient Payment Panel (a federal advisory committee that advises the Secretary on the OPPTS) provide advice on the appropriate supervision levels for hospital outpatient services. CMS' proposed policy will provide a uniform supervision standard that applies to all services and will ensure that small rural hospitals and CAHs will be able to provide sufficient access to needed services in their communities. **CHA supports CMS' proposed change which CMS should finalize.**

- **Removing Total Hip Arthroscopy (THA) from the Inpatient Only (IPO) List**

CMS proposes to remove total hip arthroscopy (THA) from the inpatient only (IPO) list on the basis that "the simplest procedure described by the code may be performed in most outpatient departments" and "the procedure is related to codes that CMS has already removed from the IPO list." While THA can 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 does not believe that the outpatient setting is a safe and appropriate for Medicare beneficiaries undergoing THA.**

THA is a significant procedure that can require a hospital stay of several days. Patients who undergo THA can experience significant post-operative pain and the ability to get appropriate and timely ancillary support can be affected by socioeconomic barriers that can often result in

delays in care. CHA believes that few, if any, Medicare beneficiaries could be safely discharged home the same day as undergoing a total hip replacement, as would occur if this procedure were furnished in a hospital outpatient setting. Providing this surgery in an outpatient setting will not afford patients enough time to recover properly or allow providers to address all post-surgical concerns—including any problems that arise with comorbidities. Same-day discharge would raise deep concerns about the safety of the home environment into which Medicare patients would be discharged, creating potential issues with patient safety and an increase in hospital admissions. **CHA opposes removing THA from the IPO list.**

Application of the two-midnight rule.

Should CMS finalize its proposal, it will be essential to ensure that the decision as to the most appropriate site where THA can be performed should be left to the patient in consultation with his/her physician. CHA is concerned that should THA be removed from the IPO list, it not be selected for medical review in each instance where the patient was admitted as an inpatient.

Under the two-midnight rule, an inpatient admission is considered reasonable and necessary when the physician expects the patient to require a stay that crosses at least two midnights. Since 2016, CMS has allowed for case-by-case exceptions to the two-midnight rule where the admitting physician does not expect the patient to require hospital care spanning two midnights but documentation in the medical record supports the physician's determination that the patient requires inpatient hospital care. Procedures on the IPO list are appropriate for inpatient hospital admission regardless of the expected length of stay. Once a procedure is removed from the IPO list, it is subject to medical review for compliance with the two-midnight rule by a Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may refer cases for further review by the RAC if the hospital has high denial rates, consistently fails to adhere to the two-midnight rule or fails to improve after BFCC-QIO educational intervention.

CMS proposes that a procedure removed from the IPO list would not be subject to referral to Recovery Audit Contractors (RAC) for compliance with the two-midnight rule within the first calendar year of their removal from the IPO list. **CHA agrees with the establishment of a moratorium on RAC referral after a procedure is removed from the IPO list and urges CMS consider a longer time period than one year.**

The two-midnight rule was established to provide guidance to physicians and hospitals when to admit patients for procedures that are commonly performed inpatient or outpatient. Procedures removed from the IPO list (including THA should CMS finalize its removal), are likely to continue being performed inpatient in the majority of instances, at least initially. A longstanding

principle of CMS' policy is stated in Chapter 1, section 10 of the Medicare Benefit Policy Manual:

The decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting.

CHA agrees that the decision whether to admit a patient as an inpatient is a complex medical judgment. For this reason, we believe strong deference should be given to the physician's decision to admit a patient for inpatient care when undertaking medical review of procedures recently removed from the IPO list. Further, the moratorium on RAC review for site of service should be continued until procedures formerly on the IPO list are more routinely performed on an outpatient basis which is likely to be more than one year.

- **Adding Total Knee Arthroplasty (TKA) to the Ambulatory Surgical Center (ASC) List**

CMS proposes to add total knee arthroplasty to the ASC list of covered procedures beginning in 2020. **CHA believes is not appropriate to add TKA to the ASC list at this time, and is concerned about the impact on beneficiary coinsurance of doing so.**

CHA is concerned that providing TKA in an ASC setting poses too great a safety risk to the Medicare population, many of whom have multiple chronic conditions. CMS has not shared data illustrating outcomes for TKA in an outpatient setting and these surgeries are still largely done on an inpatient basis, where CMS estimates 82% of all TKA surgeries were performed in 2018. In addition, CMS itself acknowledges that receiving TKA in an ASC will not be suitable for most beneficiaries. In addition, TKAs performed in an ASC could be more costly for Medicare beneficiaries. Copayments for procedures performed in hospital outpatient department are limited to the inpatient hospital deductible (\$1,364 for 2019). This is not the case in the ASC setting, which means beneficiaries will face higher out of pocket costs.

CHA recommends CMS do additional research on whether TKA is safe and appropriate in the ASC setting and for which kinds of patients, as well as consider the higher beneficiary out-of-pocket costs, before taking any action to add TKA to the ASC list.

- **Outpatient Hospital Quality Reporting Program**

CHA supports the proposed removal of the measure OP-33, External Beam Radiotherapy for Bone Metastases from the Hospital Outpatient Quality Reporting (OQR) Program beginning with the 2022 payment year. This measure was recently finalized for removal from

the PPS-exempt cancer hospital quality reporting program; it is no longer being maintained by the measure steward and lost its National Quality Forum endorsement.

Four ASC measures are being considered for possible future addition to the OQR Program, and CHA agrees that the patient safety measures relating to patient burns, falls, other never events (wrong site, wrong side, wrong patient, wrong procedure, wrong implant), and all-cause hospital transfer/admission are appropriate for consideration for the OQR Program. CHA generally believes that measures should be tested, reviewed by the Measure Applications Partnership (MAP) and endorsed by the National Quality Forum (NQF) prior to being proposed for inclusion in any Medicare quality program. If CMS works to develop an OQR Program version of ASC-4: All-Cause Hospital Transfer/Admission, consideration should be given to how it overlaps with the existing OQR Program measure OP-36: Hospital Visits after Hospital Outpatient Surgery.

- **Request for Information: Price Transparency and Quality Measurement**

As discussed in detail above, CHA does not support CMS' proposal to require hospitals to post "standard charges" - gross charges and payer-specific negotiated charges - for all items and services as well as 300 "shoppable services" because we do not believe this approach would further the goal of providing patients with accurate information about their out-of-pocket expenses for health care services. Given the limitations of the proposal, it is at least premature to consider pairing quality information with the proposed standard charge postings as contemplated under this request for information.

CHA agrees that patients should have access to quality performance information that will be useful to them in making decisions in choosing providers, and we continue to support the use of *Hospital Compare* for public display of hospital performance on standardized quality measures. We would also support efforts by CMS to work with stakeholders to find ways to make the information provided on *Hospital Compare* more user-friendly to patients.

CMS specifically asks for comments on whether the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey should be amended to add questions such as "how well did your doctor communicate the expected out-of-pocket costs for your healthcare services in advance?" or "Were you surprised by the out-of-pocket costs you had for a given procedure or hospital stay?" Although we agree that patients should always be informed in advance about the out-of-pocket costs they can expect to pay when they are admitted to the hospital for treatment, we question whether the HCAHPS is the appropriate tool for gauging patient experience with these communications. For example, patients may not be able to distinguish between out-of-pocket costs owed to the hospital for an inpatient stay and the out-of-pocket costs owed to one or more physicians who treated them during their hospital stay. Out-of-pocket costs may not be knowable before or during the stay, or even for a time period after the

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stay which means the survey could arrive before the patient has been notified of the total out of pocket cost.

In closing, thank you for the opportunity to share these comments on the proposed 2020 OPPS proposed 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, appearing to read "Lisa A. Smith". The signature is fluid and cursive, with the first name "Lisa" being more prominent than the last name "Smith".

Lisa A. Smith
Vice President
Public Policy and Advocacy