hfma
healthcare financial management association

October 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-1850

File Code: CMS-1736-P

Re: 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

Dear Administrator Verma:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the *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* hereafter referred to as the Proposed Rule) published in the Federal Register on August 12, 2020.

HFMA is a professional organization of more than 56,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction
HFMA would like to commend CMS for its thorough analysis and discussion of the many Medicare payment decisions addressed in the 2021 Proposed Rule. Our members would like to comment on the proposals related to:

- Separately Payable Drugs Provided by 340B Hospitals
- Proposed changes to the Inpatient Only (IPO) List
- Proposed Ambulatory Surgical Center (ASC) Payment and Comment Indicators
- Proposed Prior Authorization Process Requirements for Certain Outpatient Hospital Department Services

Below, please find specific comments on the items above.

Separately Payable Drugs Provided by 340B Hospitals

CMS proposes to reduce payments for separately payable drugs provided to Medicare beneficiaries by 340B hospitals to average sales price (ASP) - 34.7% plus an add-on payment of 6% for services associated with drug acquisition that are not separately paid for, such as handling, storage and other overhead. This would reduce payment for separately payable drugs that were acquired by hospitals under the 340B program from ASP - 22% to ASP - 28.7%. CMS states the intent of the payment reduction is to reduce costs for Medicare beneficiaries.

While HFMA members generally support efforts to reduce beneficiary cost sharing, we question the effectiveness of this proposal relative to the negative impact on access to care that this will impose on indigent patients. MedPAC finds that 89%[1] of Medicare beneficiaries have either Medigap coverage or Medicaid, which covers their cost sharing. For the 11% of patients who receive separately payable drugs at 340B hospitals, many (given their socioeconomic situation and their burden of illness) qualify and receive charity care discounts for their cost sharing. Therefore, on its face we continue to believe the potential number of beneficiaries who will see reduced costs as a result of this policy are greatly outweighed by the threat it poses to access to lifesaving drugs and services provided by safety net hospitals, particularly in rural areas.

CMS bases the increased reduction on a survey that was provided to 1,422 hospitals between April 24 and May 15, 2020. Respondents could either answer the "detailed survey" where they provided acquisition costs for each individual drug or biological or the "quick survey" where the hospital indicated that it preferred that CMS utilize the 340B ceiling prices obtained from the Health Resources and Services Administration. Of the responding hospitals (n=100), 7% responded using the detailed survey; 55% (n=780) responded using the quick survey option; and the remaining 38% (n=542) did not respond.

We note that the survey was fielded at a time when many hospitals were focused on reconfiguring operations and processes as a result of the COVID-19 pandemic. During this time, hospitals had limited ability to respond to an administratively burdensome survey. Many hospitals repurposed staff to support efforts to screen and deliver care to COVID-19 patients. Additionally, some hospitals were forced to furlough staff, who could have responded to this survey, to remain financially viable in the face of drastically reduced revenue resulting from complying with CMS's instructions[2] to curtail non-emergent procedures.

As discussed below, we continue to strongly believe that hospitals that provide separately payable drugs to Medicare beneficiaries acquired under the 340B program should be paid ASP+6%, like all other providers. Further, we believe it is inappropriate to base additional cuts to Medicare payments to providers for drugs acquired under the 340B program on a survey where over half of the hospitals did not respond and only 7% actually provided hospital-specific data. **Therefore, we believe any reductions in payments to 340B providers should be delayed until CMS can gather more robust data.**

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[1] MedPAC. "Medicare beneficiary and other payer financial liability."

[2] CMS. "CMS releases recommendations on adult elective surgeries, nonessential medical, surgical and dental procedures during COVID-19 response," March 18, 2020.

As in previous years,[3,4,5] **HFMA strongly opposes reducing payments to safety net hospitals for drugs acquired under the 340B program and dispensed to Medicare beneficiaries**. This payment cut is budget neutral. Therefore, reductions in payments to 340B hospitals are reallocated across the Outpatient Prospective Payment System (OPPS). For CY21, the proposed rule estimates that increasing the reduction factor for separately payable Part B drugs acquired under the 340B program will reallocate an additional estimated $427 million from safety net hospitals to all other hospitals. Given that MedPAC finds Medicare margins for not-for-profit hospitals in 2018 were -9.3%,[6] HFMA members do not dispute that outpatient payment rates need to be increased across the board to better reflect the cost of providing medically necessary services to Medicare beneficiaries. However, as in prior years, HFMA members have questioned the logic of taking additional money from not-for-profit safety net 340B hospitals and redistributing it randomly across the OPPS. COVID-19 is adding to our longstanding concern over payment reductions to 340B hospitals.

In the face of increased expenses and significant revenue losses – particularly in key outpatient services – due to the COVID-19 public health emergency, we are deeply concerned these additional cuts could accelerate safety net hospital closures. The Chartis Center for Rural Healthcare estimates more than 450 hospitals are financially vulnerable.[7] The purpose of the 340B program is to assist providers that care for a high number of low-income and uninsured patients. Any reduction of payment to 340B hospitals would create financial stress to safety net hospitals that provide care to these at-risk patients. **HFMA members reiterate that moving forward, they strongly believe that 340B hospitals should continue to be paid ASP+6% for separately payable drugs acquired under the program.**

Proposed Changes to the Inpatient Only (IPO) List

CMS proposes to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. In the first year of transition, CMS would remove 266 musculoskeletal services from the IPO list for 2021 if the rule is finalized. These MS-DRGs are listed in Table 31 of the proposed rule. For 2021 and subsequent years, CMS proposes to provide a 2-year exemption from site-of-service claim reviews by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to a Recovery Audit Contractor (RAC) nor will these procedures be reviewed by RACs for "patient status," for procedures that are removed from the IPO list.

Similar to CMS's proposals to remove Total Knee Replacement (TKR) and Total Hip Replacement (THR) from the IPO list, HFMA members are cautiously supportive of CMS's proposal to, over three years, expand the number of services Medicare will cover in an outpatient setting if the Medicare beneficiary's physician believes that is the appropriate setting of care. However, this support is predicated on CMS:

- Adjusting MS-DRG payments to address the higher cost of care for the remaining inpatient population

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[3] HFMA comment letter, Sept. 11, 2017.
[4] HFMA comment letter, Sept. 21, 2018.
[5] HFMA comment letter, Sept. 27, 2019.
[6] MedPAC. "Acute inpatient services: general short-term hospitals, inpatient psychiatric facilities."
[7] The Chartis Group, "The rural health safety net under pressure: understanding the potential impact of COVID-19," April 2020.

- Refining Advanced Payment Model (APM) target prices and benchmarks so they accurately reflect this policy change.
- Monitoring hospital quality payment and reporting programs to ensure changes in quality and cost measures are not the result of changes in policy.
- Ensuring this well intended policy change does not increase hospitals' administrative burden.

Below, please find HFMA members' specific comments on each of these items:

Adjusting MS-DRG Payments to Address the Higher Cost of Care for the Remaining Inpatient Population: HFMA members believe that as CMS removes additional MS-DRGs from the IPO list, healthier patients will be shifted into an outpatient setting, leaving sicker, more costly patients to have their procedures performed in the inpatient setting. The "weight" for MS-DRGs that the procedures in Table 31 of the proposed rule map to, like all MS-DRGs, are a blended historical average of all Medicare patients who have the diagnose(s) that require one of the procedures in Table 31. Under the scenario described above, it will be approximately two years before MS-DRG weights are based on claims experience that incorporates this policy. In the interim, hospitals will be under-reimbursed for providing medically necessary procedures to Medicare beneficiaries unless CMS proactively adjusts the weights for MS-DRGs that are impacted by this policy shift. **HFMA members believe cases fitting the following criteria could be removed from the existing data set to determine the correct MS-DRG weight if CMS decides to implement this policy:**

- **Cases with no comorbidities listed on the claim or that have a low-risk hierarchical conditions category (HCC) score**
- **Short length of stay (two days)**
- **No institutional post-acute care utilization**
- **No readmissions**

Refining Advanced Payment Model Target Prices and Benchmarks: In addition to repricing the MS-DRG itself, CMS and the Center for Medicare and Medicaid Innovation (CMMI) will need to account for this policy shift in any impacted Bundled Payments for Care Improvement-A (BPCI-A) episode target prices and the various accountable care organization (ACO) model benchmarks (Medicare Shared Savings Program, Next Gen, Direct Contracting Model) by adjusting for projected net payment differential for cases performed in the outpatient setting, changes in the number of "outlier" cases, changes in use of post-acute care sites of service, and potential changes in readmissions rates for the patients who continue to have these procedures performed in the inpatient setting once Medicare will cover them on an outpatient basis. As discussed in response to CMS's proposed Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing rule, HFMA has significant concerns about CMMI's attempt to create a site neutral target price for lower extremity joint replacement (LEJR) episodes.[8] **We believe the recommendations in that comment letter are applicable to other BPCI-A episodes impacted by expanded coverage for certain procedures in the outpatient setting and encourage CMS to adopt them in Comprehensive Care for Joint Replacement (CJR) and BPCI-A.**

[8] HFMA comment letter, April 23, 2020.

Monitoring Hospital Quality Payment and Reporting Programs: HFMA members continue to believe CMS needs to monitor and possibly adjust readmissions rates for total knee arthroplasty (TKA) and total hip arthroplasty (THA) used in the Hospital Readmissions Reduction Program and posted on the Hospital Compare website as a result of changes finalized in the 2019 and 2020 OPPS final rules.

Furthermore, if CMS expands outpatient Medicare coverage to procedures currently on the IPO list, we believe it will need to also monitor and possibly adjust both the hospital Medicare Spend Per Beneficiary (MSPB) measure and hospital HCHAPs scores to reflect changes in site of service resulting from this policy change. Similar to readmissions rates for TKA and THA, HFMA members are concerned that differential rates of adoption of performing the procedures in Table 31 across and within regions could potentially reduce hospitals' MSPB and HCHAPS scores.

Ensuring Hospital Administrative Burden Is Not Increased by Expanding Coverage for IPO Services to Outpatient Settings: HFMA appreciates that CMS is extending a two-year moratorium on BFCC-QIO) for "patient status" (that is, site-of-service) reviews for procedures that are transitioned off the IPO list. However, HFMA members are concerned that once the two-year moratorium expires for a set of procedures, this will become a de-facto site neutral payment policy, subjecting hospitals to increased administrative costs related to increased patient status reviews.

Many procedures currently on the IPO list are complex and may only be safely performed in an outpatient setting on a limited number of Medicare beneficiaries who have no comorbidities. HFMA notes that 66% of Medicare fee-for-service (FFS) beneficiaries have two or more chronic conditions.[9] Therefore, we ask that CMS take the following steps to ensure that this policy has the intended effect of allowing the physician to determine the most appropriate site of service for a Medicare beneficiary (as opposed to a BFCC-QIO auditor, who does not know the patient, with the review occurring on a retrospective basis). **First, HFMA members recommend CMS prohibit patient status reviews for any procedure that was on the IPO list as of CY20 and is performed on an emergent basis. Second, HFMA members recommend that CMS, using its existing IPO list criteria, annually update and maintain a "shadow IPO list." Similar to the existing IPO list, the "shadow IPO list" would be used to identify procedures that may be covered when performed in the outpatient setting, but are not subject to BFCC-QIO review if they are performed in an inpatient setting, regardless of when they were removed from the IPO list.** For example, let's assume CMS finalizes its proposed policy and for CY21 removes CPT Code 0098T: Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure) from the IPO list. If, using its current criteria, CPT code 0098T remained on CMS's "shadow IPO list," in CY23 these procedures would be exempt from site-of-service reviews when performed on an inpatient basis.

Proposed ASC Payment and Comment Indicators

CMS proposes in the 2020 OPPS rule to cover total hip arthroplasty (THA), CPT code 27130, when the procedure is provided in ASCs. **HFMA members conditionally support CMS's proposal. This support is directly predicated on adequately adjusting the MS-DRG payment and target prices for LEJR episodes for this significant policy shift.** Please see our specific comments related to CMS's proposal to phase out the IPO list (above) for our detailed recommendations, as these recommendations apply to THA procedures as well.

[9] CMS, "Chronic conditions among Medicare beneficiaries," 2011.

Proposed Prior Authorization Process Requirements for Certain Outpatient Hospital Department Services: Effective on July 1, 2021, CMS proposes to add the services listed in Table 53 (reproduced below) in the proposed rule to those that hospitals must submit a prior authorization request for in advance of service for the procedure to be covered.

CPT Code	Description
	Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck, anterior approach, each additional interspace
	Implanted spinal neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

CMS uses the high rate of growth in procedures in both families relative to the rest of the OPPS to justify its proposal. In the proposed rule, CMS notes that while the overall volume of Medicare outpatient department claims increased annually by 2.8% from 2007 through 2018, claims for both families of procedures increased significantly faster. For implanted neurospinal transmitters, the annual average rates of increase in volume for the three CPT codes (65630, 63685, and 63688) were 6.5%, 10.2%, and 8.8%, respectively. For cervical fusion with disk removal, the annual average rates of increase in volume between 2012 and 2018 for the two CPT codes (22551 and 22552) were 124.9%and 174.9%, respectively. Unfortunately, CMS does not provide the actual baseline and year-specific volume of procedures for each CPT code to provide additional evidence to support the need for this policy.

HFMA appreciates CMS's need to ensure appropriate utilization of outpatient services. However, we believe there may be circumstance-specific factors related to both types of procedures that have caused their utilization to increase at a rate faster than all other outpatient department services.

In the 2012 OPPS final rule, CMS removed CPT codes 22551 and 22552 from the IPO list. CMS should probably expect to see rapid growth of these procedures in the outpatient setting, given the recent change in policy. As noted above, CMS does not provide baseline and annual growth rates for readers of the rule to understand the actual magnitude of the increase in these procedures. Therefore, HFMA encourages CMS to take a more focused approach to the increase in utilization discussed in the proposed rule. Instead of potentially limiting patient access and increasing the administrative burden on all providers of these services, we recommend CMS analyze physician utilization patterns and use the BFCC-QIOs to retrospectively educate providers whose use of these procedures is statistically greater than their peers when adjusted for patient population characteristics. If providers continue to order these procedures at higher rates on a risk/patient population-adjusted basis than their peers, their claims could be subject to retrospective payment review.

Specific to procedures related to implantation of spinal neurostimulators (CPT codes 65630, 63685, and 63688) HFMA believes the increase in utilization of these procedures is likely a result of a broader societal understanding of the harms of opioid addiction and efforts by CMS and others to reduce opioid use for patients with chronic pain. Not only is there evidence that these devices reduce opioid

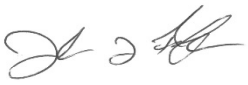
utilization[10,11] but CMS has recommended them as a strategy to manage chronic pain in lieu of long-term opioid prescribing.[12] **Therefore, given CMS's support for these devices as a way to combat the opioid addiction crisis, HFMA strongly believes that CMS should reconsider its efforts to limit access to spinal neurostimulators in the final rule.**

The CPT codes targeted by CMS's proposed prior authorization requirements are covered without prior authorization they are provided in both ASCs and physician offices. **HFMA members question why CMS has elected to place a prior authorization requirement on these procedures only when they are provided in a hospital outpatient department.**

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve the 2021 OPPS. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



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About HFMA

HFMA is the nation's leading membership organization for more than 56,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant. HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices and standards.

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[10] Kaisy, A., Van Buyten, J., Amirdelfan, K., et. al., "Opioid-sparing effects of 10kHz spinal cord stimulation: a review of clinical evidence," *Annals of the New York Academy of Sciences*, February 2020, pp. 53-64.
[11] Lamer, T.J., Moeschler, S.M., Gazelka, H.M., et al., "Spinal stimulation for the treatment of intractable spine and limb pain: A systematic review of RCTs and meta-analysis," *Mayo Clinic Proceedings*, August 2019, pp. 1475-1487.
[12] Healthcare Fraud Prevention Partnership, "Healthcare payer strategies to reduce the harms of opioids," January 2017.