The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1736-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Proposed Rule, August 12, 2020

Dear Administrator Verma:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 240 member institutions, we appreciate the opportunity to comment about the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system proposed rule for calendar year (CY) 2021.

HAP adamantly opposes the proposed payment cuts for 340B drugs. Further reductions will undermine the program and are in conflict with Congress' clear intent.

We also reiterate our position against continuing site-neutral payment reductions. CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted provider-based hospital outpatient departments, repay hospitals for the 2019 and 2020 payment reduction; and not finalize the proposed 2021 policy.

Importantly, as the agency did in the CY 2021 Physician Fee Schedule, we urge CMS to make every effort to continue the telehealth flexibilities granted during the COVID-19 pandemic.

The following comment letter also addresses changes to:

- Supervision for hospital outpatient therapeutic services
- Prior authorization requirements
- Changes to inpatient-only (IPO) list
- Hospital star ratings methodology changes

In addition, we incorporate, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule.

Thank you for your consideration of HAP's comments about this proposed rule regarding outpatient payment and other provisions related to hospitals and the patients they serve in Pennsylvania.

If you have any questions, contact Kate Slatt, vice president, innovative payment and care delivery, at (717) 561-5317.

Sincerely,

Jeffrey Bechtel
Senior Vice President, Health Economics and Policy

Attachment

HAP Comments—Outpatient Prospective Payment System
Proposed Rule for Calendar Year 2021

PROPOSED 2021 PAYMENT METHODOLOGY FOR 340B PURCHASED DRUGS

Section 340B of the Public Health Service Act (340B) allows participating hospitals and other providers to purchase certain covered outpatient drugs from manufacturers at discounted prices. In the CY 2018 OPPS/ASC final rule, CMS reexamined the prior Average Sale Price (ASP) plus 6 percent payment methodology for drugs acquired through the 340B Program. Beginning January 1, 2018, Medicare adopted a policy to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. That reduction has been subject to ongoing litigation but was upheld by the U.S. Court of Appeals for the District of Columbia Circuit on July 31, 2020, when it overturned a lower court's decision in favor of hospitals. However, hospitals are seeking a rehearing by the full court and this matter has not yet reached final legal disposition.

HAP strongly opposes the proposed rule's deepening of cuts in payments for 340B drugs. In the 2021 proposed rule, CMS puts forth a new payment policy for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program that extends reimbursement cuts for another year. As noted in previous comments, we believe these cuts deny Congress' clear intent for the 340B program and exacerbate the already significant strain placed on hospitals serving vulnerable communities.

Beginning in 2021, the agency proposes to pay certain 340B hospitals for drugs purchased through the 340B program at Average Sales Price (ASP) minus 34.7 percent, plus an add-on of 6 percent of the product's ASP for overhead and handling, to reach a net payment rate of ASP minus 28.7 percent. As in previous OPPS rules, this proposed policy also applies to 340B acquired drugs furnished in non-grandfathered (non-excepted) off-campus provider-based departments and applies to biosimilar drugs and other drugs without an ASP purchased through the 340B program. ***HAP adamantly opposes both the deepening of the cuts and the broader application of the policy as running contrary to the very important intent of the program to allow covered entities to stretch scarce resources to reach more eligible patients and providing more comprehensive services.***

Concerns with the CMS Hospital Acquisition Cost Survey

According to the agency, this new proposed payment is based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs from spring 2020. In its proposed rule, CMS provides a detailed discussion of the survey results and the methodology applied in developing this proposal. Essentially, CMS defends the new policy by noting that it is less of a reduction than what would have been established if the agency relied on the survey data alone, without applying additional analytics and data trimming.

However, HAP and the hospital community had significant concerns about the survey when it was issued and we have even greater concerns about using the results as the basis for change. First, CMS surveyed 340B hospitals *only*; in order to get accurate and complete information and we believe that *all* hospitals should have been surveyed to collect data for cost analysis. Second, only two quarters of data was collected to set rates for a whole year. CMS should consider a full year of data, at minimum, before making changes to payment policy. Finally, of the 340B hospitals that were surveyed, 38 percent did not respond at all and only about 7 percent of respondents sent data at a National Drug Code (NDC) level. For these reasons and others, HAP strongly believes that both the methodology and the sample size were inadequate to use for establishing a broad payment policy change.

CMS Solicits Comments on Continuation of ASP Minus 22.5 Percent

In an unusual move, while CMS is proposing a new payment policy for 2021, the agency is simultaneously seeking comments on an alternative proposal of continuing the current Medicare payment policy of paying ASP minus 22.5 percent for 340B-acquired drugs for calendar year 2021 and subsequent years. HAP is concerned about this request because in effect it potentially presents hospitals with a false choice—the current proposal for 2021, which we oppose, and the policy in place, which we also oppose.

Potential 340B Remedies

Should the court ultimately find in favor of hospitals and determine that the nearly 30 percent reduction in reimbursement for certain 340B hospitals was unlawful for years 2018, 2019 and potentially 2020, HAP believes the remedy should be as follows: **Refund payments should be made to each affected 340B hospital and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 hospital OPPS rules, and others not adversely impacted by the reductions should be held harmless.** This remedy would not disrupt the Medicare program and is consistent with those for past violations of law.

In summary, for more than 25 years, the 340B program has helped hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services to vulnerable communities. CMS' current proposal to change the 340B payment policy will result in the continued loss of resources at the worst possible time, as 340B hospitals in Pennsylvania and across the country are battling a national pandemic. As a result, **HAP strongly opposes the proposed 2021 payment policy and urges the agency to restore 340B reimbursement to ASP plus 6 percent for all 340B hospitals.**

CONTINUED PHASE-IN OF MEDICARE'S SITE-NEUTRAL PAYMENT POLICIES

In the CY 2019 OPPS proposed rule, CMS described "unnecessary" increases in the volume of hospital outpatient clinic visits in excepted off-campus provider-based departments (PBDs) and, citing its authority under section 1833(t)(2)(F) of the Social Security Act (SSA), proposed to pay for clinic visits furnished in excepted off-campus PBDs at an amount that equals 40 percent of the OPPS rate. CMS further proposed to implement this proposal in a non-budget neutral manner.

Despite the many concerns and objections raised by HAP, the AHA, and other commenters, CMS's CY 2019 OPPS final rule adopted the proposal to cut payments to excepted PBDs and make the cuts in a non-budget neutral manner and adopted the continuation of this policy in the CY 2020 OPPS rule.

The AHA, three of its member hospitals and the Association of American Medical Colleges (AAMC) filed suit in January 2019 to challenge the new clinic visit payment policy, arguing hospitals with excepted off-campus PBDs faced imminent injury as a result of CMS's unlawful decision to reduce clinic visit payment rates and to do so in a non-budget neutral manner.

While the court originally found that the agency exceeded its statutory authority when it cut the payment rate for clinic services at excepted off-campus provider based clinics, that decision has been overturned. The litigants are seeking a rehearing by the full U.S. Court of Appeals for the District of Columbia Circuit.

Despite ongoing legal action, in this rule, CMS proposes to continue the payment cut for CY 2021.

HAP reiterates its comments from the previous year's proposed rule and incorporates, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule. We, therefore, urge CMS to:

1. ***Immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts***
2. ***Promptly repay hospitals the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates***
3. ***Abandon the proposed continuation of the payment cut in 2021***

PRIOR AUTHORIZATION REQUIREMENTS

In an attempt to slow "unnecessary increases in the volume" of certain covered outpatient department services, often considered cosmetic, the rule proposes new prior authorization requirements for two service categories:

- Cervical fusion with disc removal
- Implanted spinal neurostimulators

Slated to begin with dates of service on or after July 1, 2021, the prior authorization process would require hospitals to obtain provisional affirmation before the medically necessary service is furnished or billed to Medicare. Claims with services requiring authorization received without provisional affirmation will be denied. There is an expedited process available in cases of emergency and a process to resubmit a request for authorization with additional documentation in the event the initial request is denied. CMS has also included a provision that would allow them to exempt a provider from the prior authorization process if they achieve a prior authorization provision affirmation threshold of at least 90 percent during a semiannual assessment.

While HAP appreciates the agency's desire to control excess utilization of "unnecessary" services, increasing the number of services requiring prior authorization will lead to additional time spent on paperwork, rather than clinician time at the bedside. This is counter to CMS's expressed goal of "Patients over Paperwork."

There are many other plausible reasons for seeing an increase in the volume of these services during the years CMS reviewed claims (2007–2018). For example, the cervical fusion with disc removal procedure and the neurostimulators are used to relieve chronic pain when non-surgical methods are unsuccessful. There has been significant forward motion in addressing the opioid crisis in this country as evidenced by CMS issuing its own Opioid Misuse Strategy in 2017 and non-pharmacologic methods are the preferred method for pain management, of which both of these procedures are included. Additionally, a study performed by Watson Policy Analysis showed that cervical fusion outpatient service increases were related to decreases in the inpatient volume. The increase in the outpatient setting also coincides with the removal of CPT code 52251 and the add-on code, 22552 from the IPO which would also result in additional volume funneling through the outpatient setting. Attaching onerous prior authorization requirements could limit beneficiaries' access to these critical procedures.

HAP urges CMS to withdraw this proposal and to continue efforts to work with stakeholders to provide meaningful outreach and education related to billing Medicare for these services only when medically necessary rather than implementing cumbersome, administrative, solutions.

CHANGES TO INPATIENT-ONLY (IPO) LIST

CMS designates certain procedures that can only be performed in an inpatient setting for various reasons such as the acuity of the procedure, history of the patient, or postoperative recovery time. The list is typically reviewed by CMS annually.

This year, CMS is proposing to completely eliminate the IPO list over a three-year period, from 2021 through 2024 and proposes to begin this process with the elimination of 266 musculoskeletal services from the IPO list. As part of its explanation, CMS states that it believes clinicians should ultimately use their clinical judgement based on the needs of the beneficiary in selecting a site of service.

HAP encourages CMS to refrain from eliminating the IPO in its entirety to ensure the safety of its beneficiaries. Many procedures included on the list are high risk, invasive, complex procedures and warrant the inpatient care setting. In the event that CMS finalizes the elimination of the IPO list, HAP strongly suggests that CMS identify the complex, invasive procedures that would most likely be better served in an inpatient setting and defer to physician deference for site of service decisions. These specific services should be exempt from medical review for site of service and the two-midnight requirement.

HAP also encourages CMS to consider the following adjustments for the bundled payment initiatives sure to be affected:

- ***Incorporate risk-adjustment methodology in the comprehensive care for joint replacement model (CJR), and bundled payments for care improvement (BPCI) programs to ensure that actual performance can be accurately compared to historical performance based on the populations being served in each time period***
- ***Evaluate including outpatient THA in the CJR and BPCI programs for hospital outpatient departments only***

In regards to the proposal to remove 266 musculoskeletal services from the IPO list, HAP has significant concern that we have not had adequate time to review and analyze the proposal. We urge CMS to refrain from finalizing this proposal until a detailed analysis regarding the safety of removing each service is completed.

HOSPITAL STARS RATING METHODOLOGY

In an attempt to address concern since CMS began to report an overall star rating in 2016, the rule proposes an overhaul to the current overall hospital star rating methodology including:

- Reorganizing the star rating measure groups

- Eliminating the use of latent variable modeling
- Assigning hospitals to one of five peer groups based on their proportion of dual-eligible patients similar to the methodology used by the Hospital Readmissions Reduction program (HRRP)
- Placing hospitals into one of three peer groups based on the number of measure groups it reports

These proposals are an attempt to simplify what has been considered a complex, flawed methodology. CMS notes that its aligning with HRRP should not be considered intent to incorporate social risk factor adjustment into the methodology but simply align the two efforts. It also notes that should this step be removed from HRRP, it too would be removed from the stars methodology.

HAP is pleased to see CMS move towards creating more transparency by simplifying the overall stars rating methodology. HAP supports CMS' effort to include peer group analysis but notes the support is very much tied to the need to address social risk adjustments in all quality and performance programs and should remain in the methodology for both HRRP and the hospitals stars rating. HAP also believes that more needs to be done to ensure the accuracy of the stars rating system and should engage stakeholders in this work.

In addition to convening stakeholders, HAP urges CMS to consider resigning the overall single composite score and replace it with ratings for subsets of measures which would be more meaningful and accurate.

SUPERVISION FOR HOSPITAL OUPATIENT THERAPEUTIC SERVICES

In CY 2020, CMS finalized a proposal to change the minimum required level of supervision from direct to general supervision for all outpatient therapeutic services provided by all hospitals and CAHs. General supervision means that services are furnished under a physician's direction and control, but does not require a physician's actual presence during the delivery of the services.

This change did not apply to some groups of services such as non-surgical extended duration therapeutic services (NSEDTS) and pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation. These services still require a level of supervision that is higher than general.

During the COVID-19 pandemic, CMS provided flexibilities to Medicare providers including reducing the level of supervision for NSEDTS to general supervision for the entire service. CMS also allowed for the requirement of direct physician supervision of pulmonary rehabilitation,

cardiac rehabilitation, and intensive cardiac rehabilitation services to be met virtually through real-time audio/visual communications technology to reduce risk of exposure.

In the rule, CMS proposes to make these changes permanent. Specifically, it proposes to change the level of supervision required for NSEDTS to general and to allow for a virtual presence in order to meet the requirement for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. More specifically, the rule proposes that the virtual direct supervision would require real-time presence via audio/video technology through the entirety of the procedure rather than just availability during this time.

HAP is pleased to see a proposal for a permanent fix and urges CMS to finalize the change from direct to general supervision for NSEDTS and allowing for virtual direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. However, HAP is concerned that real-time presence of a physician for supervision during the entirety of a procedure is more intensive than the current in-person requirements for direct supervision, which require that a physician is immediately available. HAP urges CMS revise this requirement to mirror the current in-person direct supervision requirements.

TELEHEALTH FLEXIBILITIES

Undoubtedly, the COVID-19 pandemic has created a world of uncertainty for patients and their health care providers. While a grim reality, the pandemic has also been the impetus for advancing access to health care through technology ten-fold. Beneficiaries have been able to continue to see their health care provider and do so safely in the comfort of their own home and will continue to demand access to telehealth when clinically appropriate.

HAP urges CMS to make broad, permanent adoption of any services that were acceptable during the pandemic given that only services that did not pose significant patient-safety concerns were added to the list during this time. HAP urges CMS to continue to be flexible in considering additional services as we continue in this emergency.