

## CMS PROPOSES PAYMENT POLICY CHANGES IMPACTING HOSPITAL OUTPATIENT DEPARTMENT SERVICES - WHAT YOU NEED TO KNOW

On July 29, 2019, the Centers for Medicare & Medicaid Services ("CMS") released its **proposed rule** for Calendar Year ("CY") 2020 Hospital Outpatient Prospective Payment System ("Proposed Rule"). Among many other changes, CMS proposed three key payment policy updates impacting hospital outpatient departments, including: (1) lowering the supervision standard for hospital outpatient therapeutic services from direct supervision to general supervision; (2) requiring prior authorizations for certain hospital outpatient department services; and (3) reducing payments for clinic visits at off-campus provider-based departments ("PBDs"); and (4) the first ever set of proposed rules implementing the Affordable Care Act's requirement, added at §2718(e) of the Public Health Service Act, related to price transparency and requiring hospitals to publish their standard charges. The Proposed Rule also addresses the pending litigation involving Medicare payment cuts for drugs purchased under the 340B program (from ASP+6 percent to ASP-22.5 percent), including possible retroactive payment adjustments and the possibility of reducing the cuts prospectively (ASP +3%). We recently detailed this significant development in another Hall Render **alert**. We encourage hospital providers to submit comments on the OPPS Proposed Rule to ensure adequate and appropriate payment to hospitals and that the industry's concerns for addressing price transparency initiatives are appropriately considered.

### GENERAL SUPERVISION STANDARD FOR SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

It has been a longstanding CMS payment policy to require direct supervision for hospital outpatient therapeutic services furnished in hospitals and PBDs of hospitals as set forth in 42 CFR § 410.27. In the CY 2010 OPPS final rule, CMS clarified that this standard applies to critical access hospitals ("CAHs") as well as hospitals paid under the OPPS. The CAH and small rural hospital community raised concerns they would be unable meet the direct supervision standard due to recruiting and staffing challenges. In response to these concerns, on March 15, 2010, CMS instructed the Medicare Administrative Contractors ("MACs") to not enforce the direct supervision requirement for hospital outpatient therapeutic services rendered in CAHs from January 1, 2010 through December 31, 2010.

As a result of continued concerns from the rural hospital community, CMS extended this notice of nonenforcement ("enforcement instruction") as an interim measure for CY 2011 and expanded it to apply to small rural hospitals having 100 or fewer beds. Since that time, either CMS or Congress has continuously extended nonenforcement of the direct supervision standard, which remains in effect through December 31, 2019. Extension of the enforcement instruction and legislative actions that have been in place since 2010 have created a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program, with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds.

For CY 2020, CMS proposed to end the two-tiered system of supervision by uniformly requiring general supervision for all hospital outpatient therapeutic services provided by hospitals and CAHs. As defined under 42 CFR § 410.32(b)(3)(i), "general supervision" means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. This proposal would ensure a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service.

Although CMS lowered the supervision standard for hospital outpatient therapeutic services, it noted that it will retain the ability to consider a change to the supervision level through notice and comment rulemaking if an individual hospital outpatient therapeutic services is more stringent than general supervision. Additionally, CMS seeks public comment on whether specific types of services, such as chemotherapy administration or radiation therapy, should be excepted from this proposal.

### PRIOR AUTHORIZATION PROCESS FOR CERTAIN HOSPITAL OUTPATIENT DEPARTMENT SERVICES

CMS has identified a significant increase in the utilization volume of certain hospital outpatient therapeutic services that may be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures that are not covered by Medicare, but these services may be combined with or masquerading as covered therapeutic services. These service categories include: (1) blepharoplasty; (2) botulinum toxin

injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation (“Service Categories”).

CMS is proposing a new authorization process for these outpatient department Service Categories with specific CPT codes that will be published by CMS. Specifically, CMS proposed as a new regulation at § 419.82 that as a condition of Medicare payment, a provider must submit a prior authorization request for a hospital outpatient department requiring prior authorization to CMS. The prior authorization request must include all documentation necessary to show the service meets applicable Medicare coverage, coding and payment rules, and the request must be submitted before the service is furnished to the beneficiary and before the claim is submitted. If the request meets the applicable Medicare coverage, coding and payment rules, CMS or its contractor would issue a provisional affirmation to the requesting provider. If the request does not meet the applicable Medicare coverage, coding and payment rules, CMS or its contractor would issue a non-affirmation decision to the requesting provider within 10 business days. If a provider receives a non-affirmation decision, the provider may resubmit a prior authorization request with any applicable additional relevant documentation. Additionally, an expedited review process would be available when requested by a provider and CMS or its contractor determines that a delay could seriously jeopardize the beneficiary’s life, health or ability to regain maximum function.

Claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt from the prior authorization process. CMS may elect to exempt a provider upon a provider’s demonstration of compliance with Medicare coverage, coding and payment rules by achieving a provision affirmation threshold of at least 90 percent during a semiannual assessment. In the event the cost of the prior authorization program exceeds the savings it generates, CMS proposes to reserve the right to suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS’s web page.

## **REDUCTION IN PAYMENTS FOR CLINIC VISITS AT OFF-CAMPUS PROVIDER-BASED HOSPITAL DEPARTMENTS**

In the CY 2019 OPPS Final Rule, CMS finalized its proposal to reduce payment for evaluation and management (“E/M”) services (as described by HCPCS code G0463) at *all* off-campus PBDs with the payment impact to be phased in over a two-year period. CMS noted that clinic visits (i.e., HCPCS code G0463) are the most common services billed under the OPPS and are also furnished in the physician office setting. Accordingly, CMS targeted this service in an attempt to control the volume of these services under the OPPS. It is important to note that on-campus PBDs (including those on the campus of a remote location) and dedicated emergency departments are excluded from these payment cuts since they do not use the PO modifier. A more detailed discussion of this payment reduction policy is available in our [previous article](#).

In CY 2019, CMS finalized that the reduction in payment for off-campus E/M services would be made over two years. CY 2020 will be the second year of the two-year transition of this policy, and in CY 2020, these departments will be paid the site-specific Medicare Physician Fee Schedule rate for the clinic visit service. In other words, under the payment policy reduction, if a hospital bills for an E/M service at an excepted (grandfathered) off-campus PBD, as indicated by billing with the PO modifier, it would be paid at 40 percent of the OPPS rate in 2020 (a 60 percent payment reduction).

It is also important to note that there are several pending legal challenges to this policy of reducing payments for E/M services being applied at PBDs excepted from the payment cuts under Section 603 of the Bipartisan Budget Act of 2015.

## **PROPOSED REQUIREMENTS OF HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES**

In the FFY 2019 final inpatient PPS rule CMS reminded hospitals of their obligation to comply with §2718(e) of the PHS Act to make available a list of their standard charges and provided subregulatory guidelines that became effective January 1, 2019. This guidance was very general and left a lot to provider interpretation. Now, CMS has for the first time proposed specific regulations for implementing this price transparency initiative. The proposed rule defines “hospital,” “items and services” and “standard charges.” It also proposes requirements for “consumer friendly display” of “payer-specific negotiated charges for selected shoppable services.” A full analysis of this aspect of the Proposed Rule is beyond the scope of this bulletin, so watch for additional bulletins addressing this aspect of the Proposed Rule.

## **PRACTICAL TAKEAWAYS**

If CMS’s proposals are adopted in the final rule, which is issued sometime in November, then beginning January 1, 2020 the following principles will apply:

- Outpatient therapeutic services at all hospitals and CAHs would require general supervision to match the policy previously applied at

CAHs and small rural hospitals. If adopted, hospital will need to assess patient care needs when assessing the level of supervision that it will require.

- CMS may require more stringent supervision – either direct or personal – on a service specific basis.
- CMS would establish a prior authorization process for at least the following services: (1) blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation.
- CMS will continue to phase in its payment reductions for E/M clinic visits at excepted (grandfathered) off-campus PBDs. In 2020, such services will be paid at 40 percent of the OPPS rate. Hospitals should analyze the impact of this reduction in payments.
- Hospitals need to review the price transparency proposals and provide comments on this significant development.

Stakeholders are strongly encouraged to submit comments to CMS. Comments are due no later than 5:00 PM EDT on September 27, 2019.

If you have questions or would like additional information about this topic, please contact:

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