

September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1678-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; published at Federal Register, Vol. 82, No. 138, July 20, 2017.

Submitted electronically via www.regulations.gov

Dear Ms. Verma,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on the proposed rule. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 38 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

UPH appreciates the time and effort of CMS in developing and proposing this rule and respectfully offer the following comments.

340B DRUG PRICING

CMS is proposing to reduce the payment for non-pass-through, separately payable drugs purchased by 340B-participating hospitals through the 340B drug pricing program. The proposed payment rate is the average sales price (ASP) minus 22.5 percent instead of ASP+6 percent – a total reduction of nearly 30%. In addition, CMS is seeking input on how to apply all or part of the savings generated by this payment reduction and whether to target hospitals that treat a large share of indigent patients, especially uninsured.

- ***Comment:*** This policy change impacts 11 of our nonprofit hospitals across Illinois, Iowa and Wisconsin that are eligible for the 340B Drug Pricing Program – 9 are eligible due to Medicare disproportionate share hospital status and 2 are sole community hospitals. It is estimated that

UPH will receive \$44.6 million this year in total savings from 340B program (an average of \$4.5 million per hospital). **UPH strenuously opposes this drastic reduction and its impact on our ability to provide outreach and needed services in our communities.**

- 340B proposal targets DSH Hospitals with greater uncompensated care. Not all DSH hospitals are on a level playing field. 340B DSH hospitals account for only about one third of DSH hospitals, but provide nearly 60% of all uncompensated care. By reducing this reimbursement, it places a greater financial strain on DSH hospitals that are already being financially stretched. **In 2016, the savings estimated from the 340B program contributed from 23% to over 100% of our total operating margin for our participating hospitals.**
- 340B proposal does not impact ever-increasing drug prices. Although this proposal does lower reimbursement paid by Medicare for certain drugs, **the proposed rule does not reduce drug manufacturers' prices.** This proposal does not push the needle on the important issue of drug pricing generally and it avoids changes to manufacturer price setting nor ultimately does not impact prices charged to wholesalers or providers. As such, this proposal does nothing to lower drug prices for patients filling prescriptions via Medicare Part D which seems to be a much larger need for our patients.
- 340B proposal adversely impacts services to vulnerable individuals and communities. 340B program funding reaches far beyond enhanced programming by our pharmacies and staff to outreach to patients. UPH uses 340B funding for a variety of purposes within our community initiatives, whether it is seed money for innovative projects, sustainability funding for community-driven programs, or gap-fillers (replacing decreases in revenue or funding commitments) to keep operations afloat. **340B program savings only represents approximately 15% of UPH uncompensated care and reduces drug spending by a similar amount.** The reinvestment of 340B program savings funded in part child protection centers, dental clinics, community mental health services, prenatal outreach and childbirth classes, and free primary care clinics beyond enhancements to our pharmacy service delivery infrastructure.
- 340B proposal requires coding changes and expenses for all hospitals regardless of 340B participation. CMS is proposing every hospital insert a claims modifier to indicate that a drug was not purchased at 340B prices on Part B invoices for separately payable drugs. Any omission of the modifier will result in reimbursement at the reduced ASP -22.5%. **All hospitals will need to invest in EMR coding and training to reflect this change,** with the assumption being that drugs automatically receive the reduced ASP amount in the absence of the modifier.

Despite our concerns with the current proposal, UPH does not take the position that the 340B drug pricing program should remain as currently structured. We do believe that 340B is challenging to administer, its regulations are subject to varied interpretation, and its operational directives would benefit from streamlining and a reduction in administrative burden. We also believe that participant hospitals should be more transparent and accountable for their use of 340B savings. **As such, UPH supports the August 21st recommendations of the Medicare Advisory Panel on Outpatient Hospital Payment to “not finalize” the proposed rule, to gather more data**

on program implementation, and to further assess the proposal's regulatory burdens. We urge CMS and HRSA to involve 340B hospitals in any restructuring efforts.

PAYMENT FOR CERTAIN ITEMS AND SERVICES FURNISHED BY CERTAIN OFF-CAMPUS DEPARTMENTS OF A PROVIDER

Section 603 of the Bipartisan Budget Act of 2015 changed the reimbursement structure for off-campus provider-based departments (PBDs). In general, existing off-campus PBDs are eligible for reimbursement under the Outpatient Prospective Payment System (OPPS), while new off-campus PBDs must seek reimbursement under a separate fee schedule. In this proposed rule, CMS refers stakeholders to CY 2018 Medicare Physician Fee Schedule proposed rule for proposed payment rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of hospitals.

- ***Comment:*** UPH has submitted comments to oppose any changes to the payment rate for nonexcepted off-campus provider-based departments of hospitals until CMS can base rates on data and accompanying analysis. CMS should not ask hospitals to bear the brunt of imprecise estimates, which will adversely impact patient access to services in vulnerable communities.

CHANGES TO THE INPATIENT ONLY LIST

For CY 2018, CMS is proposing to remove total knee arthroplasty (TKA) from the Inpatient Only (IPO) list. CMS also seeks comment regarding whether partial and total hip arthroplasty should be removed from the IPO list.

- ***Comment:*** UPH opposes the removal of total knee arthroplasty from the IPO list. We do not believe that this procedure meets the majority of criteria for list removal, nor do we believe that the Medicare and commercial populations are similarly situated as to expect similar outcomes. We question whether this policy should change without support from specific Medicare demonstrations that compare inpatient and outpatient procedures and without some standardization of exclusionary criteria. We will address each concern.
 - ***Criteria for List Removal:*** As background, CMS considers five criteria when determining whether to remove a procedure from the IPO list. CMS emphasizes that all five criteria do not need to be met to justify a removal decision. The criteria are:
 1. Most outpatient departments are equipped to provide the services to the Medicare population.
 2. The simplest procedure described by the code may be performed in most outpatient departments.
 3. The procedure is related to codes that we have already removed from the IPO list.
 4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
 5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

CMS states that criteria 1, 2 and 4 are met by the TKA procedure and is soliciting comments related to whether criteria 3 and 5 would also apply.

We do not agree that criteria 4 is met. While “numerous” is not defined, we do not believe that a substantial cohort of outpatient providers is presently performing TKAs. When responding to the question “is a short-stay hip or knee replacement right for you?”, the American Association of Hip and Knee Replacement Surgeons states:

*Outpatient total joint arthroplasty (TJA) is now being performed in **select centers on select patients** who are healthy enough to be candidates for this pathway. These surgeries can be done at an ambulatory surgery center or an inpatient hospital. Orthopedic surgeons agree that outpatient TJA should only be done on patients who are healthy enough to have surgery in such a setting and have the appropriate home setting/support to allow them to be discharged in this manner. **This concept is new, and orthopedic surgeons are still clarifying how to maximize the benefits of this idea for patients.**¹ [bold added]*

When the professional association for this specialty labels this outpatient concept as “new” and one in which realizing patient benefits is still being clarified, experience from the commercial setting does not appear conclusive or being implemented by numerous providers. Aligned with CMS’ omission of criteria 3 and 5 from the “met” criteria, we find no evidence to support their inclusion. Therefore, with criteria 4 in doubt and added to criteria 3 and 5, we do not believe that the remaining criteria have the strength to warrant the exclusion of TKA from the IPO list.

- Medicare versus Commercial Population: We agree with prior commenters that commercial experience with outpatient TKA “tend to be younger, more active, have fewer complications, and have more at home support than most Medicare beneficiaries.” These populations are not similarly situated. Although we understand that IPO removal does not mandate an outpatient procedure, this option does establish outpatient as a viable setting. While an outpatient setting may be appropriate for a younger and healthier commercial population, we are concerned that this establishes false expectations for the vast majority of Medicare beneficiaries.
- Lack of Study on the Medicare Population: We encourage CMS to delay list removal until there is an ample evidence basis from the Medicare population to support a change in setting. In addition, we would recommend that any pilot or trial to elect an outpatient procedure only be permitted for providers participating in an Advanced Alternative Payment Model. This would encourage providers to transition to risk-based service delivery models and also provide a platform to develop best practices in terms of workflows, beneficiary eligibility, and quality outcomes.
- Lack of Standardization related to Exclusionary Criteria: While CMS states that “We expect providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure”, we are concerned that CMS offers no minimum expectations in this arena. When moving procedures

¹ American Association of Hip and Knee Surgeons, “What You Should Know about Outpatient Hip or Knee Replacement,” <http://www.aahks.org/care-for-hips-and-knees/what-you-should-know-about-outpatient-hip-or-knee-replacement/> accessed September 1, 2017.

from the list, we believe that CMS should suggest at least minimum exclusionary circumstances based on evidence-based safety criteria.

UPH also opposes the removal of partial and total hip arthroplasty from the IPO list. Building upon our concerns with removal of TKA from the IPO list, we have similar concerns with partial and total hip arthroplasty.

SUPERVISION OF HOSPITAL OUTPATIENT THERAPEUTIC SERVICES

CMS is proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and 2019.

- ***Comment:*** UPH is affiliated with 18 CAHs and small rural hospitals in Illinois, Iowa and Wisconsin. **UPH supports the proposal for nonenforcement of the direct supervision instruction and requests supplemental definitions.** For non-emergency service that rural providers chose to deliver, UPH believes that the quality of care should be equal to urban areas. In that spirit, our CAHs have created workflows and work arounds with existing staff in order to comply with these requirements; however, it is unclear whether these work arounds will meet CMS expectations. We wholeheartedly agree with concerns identified by MedPAC in its September 8th meeting that CMS needs to provide further clarity by defining “immediate available” and “interruptible” as well as provide minimum time parameters required for a physician to arrive onsite, if needed.

We are pleased to provide comments to the proposed regulations and their impact on our integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Sabra Rosener
Vice President / Government Relations Officer