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To: IHCC Members

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Re: Addressing CMS' Site Neutral Payment Policy Initiatives

Summary
First, CMS has exceeded the Congress's intent in regulatorily implementing Section 603 of the 2015 Balanced Budget Act. Second, site neutral works in abstraction but not in application. As applied or in practice, site neutral payments enjoy little or no supportive evidence. Site neutral payments do not account for non-comparable patient populations thereby creating an unlevel playing field. Third, CMS has moved beyond HOPD in its zeal to impose site neutral policy more broadly, for example, in CMMI demonstrations. Moreover, site neutral payments do not move past MedPAC's long-standing criticism that CMS needs to move beyond "just blindly paying FFS [Fee for Service] rates" or more towards recognizing and rewarding value or spending efficiency.

Background
Based in part on a March 2014 MedPAC recommendation that the Congress eliminate the differences in payment rates between hospital Out Patient Physician Departments or HOPDs (CMS terms these Provider Based Departments or PBDs) and freestanding physician offices, the Congress in its November 2, 2015 Balanced Budget Act included Section 603 that made payments to certain HOPDs site neutral. MedPAC's recommendation was based in part on a previous 2012 MedPAC recommendation that called for aligning HOPD Evaluation and Management (E&M) reimbursement with that of freestanding physician offices. "On campus," or those within 250 yards of a hospital or a remote location of a hospital, were exempted from this policy as were dedicated off campus emergency departments and Critical Access Hospitals.

More specifically, HOPDs that were not billing as of November 2, 2015 or those not defined as excepted or grandfathered, would, effective January 1, 2017, no longer be reimbursed under the Out-Patient Prospective Payment System (OPPS). Instead, the Congress determined non-excepted or grandfathered HOPDs were to be paid under an "applicable payment system" under Medicare Part B. The 2017 final OPPS rule established the Medicare Physician Fee Schedule (PFS) as the ''applicable payment system."

MedPAC's 2014 site neutral recommendation was based on its finding that HOPD reimbursement under the OPPS could be more than two times that of the PFS for the same service. Site neutral payment would therefore reduce HOPD spending, MedPAC estimated, by 2.7% and overall Medicare spending by 0.6%. Site neutral payment would also, MedPAC

argued, reduce beneficiary cost sharing and presumably drive care to the most efficient delivery site.

Overview of Regulatory Implementation
Here is an overview of Section 603's implementation to date:

2017 Policies
- The site neutral payment rate would generally be 50% of the OPPS rate.
- Reduced payments would not apply to exempted HOPDs that expand services.
- Relocating an existing HOPD would result in the HOPD losing its exempted status.
- Change of ownership would not cause an HOPD to lose its exempted status if the new owner accepted the existing Medicare provider agreement from the prior owner.

2018 Policies
- Payment for items and services furnished by nonexcepted HOPDs would generally be reimbursed at a rate of 40% of the applicable OPPS rate for 2018.
- CMS also adopted a related HOPD excepted or grandfathered policy regarding separately payable, nonpass-through drugs and biologicals (other than vaccines) purchased via the 340B Program. CMS would pay excepted HOPD providers the average sales price (ASP) minus 22.5% rather than ASP plus 6%. Rural Sole Community Hospitals, PPS-exempt Cancer Hospitals, and Children's Hospitals would be excepted from this policy.

2019 Policies
- CMS expanded site neutral payments to include "clinic visits" (HCPCS Code G0463) in excepted or grandfathered off campus HOPDs. Code G0463 represents approximately 50% of all services furnished in HOPDs annually. The policy would be implemented over two years and in a non-budget neutral manner.
- CMS extended its 2018 HOPD excepted 340B-acquired drugs and biologicals payment policy to non-excepted HOPDs meaning both would now be reimbursed Average Sales Price (ASP) minus 22.5% for 340B drugs.
- CMS added a new HCPCS modifier "ER" for HOPD furnished services in off campus emergency departments (ED) such that CMS can track these services if the agency chose to lower OPPS payment rates for emergency department services in the future.
- As in 2016 CMS again proposed, but did not finalize, paying excepted HOPDs the OPPS rate for services only if these services were in the same clinical family of services that a specific HOPD location had provided and billed prior to November 2, 2015.

2020 Proposed Policies
- CMS is proposing to implement the second year of its payment modification for "clinic visits" (HCPCS Code G0463) in excepted off campus HOPDs – again in a non-budget neutral manner.

Budgetary Impact
As context:
- CMS scored Section 603 of the 2015 BBA as saving $9.3 billion over the 10-year budget window.

- Hospitals are reimbursed approximately $75 billion annually for outpatient services.
- In 2017, total Medicare benefit payments totaled $702 billion.
- Fee for Service and Medicare Advantage spending for Part A was $293 billion, for Part B $309 billion and for Part D $100 billion.
- MA spending alone for Part A and B in 2017 was $210 billion.

2017: In the 2017 final rule CMS estimated Part B spending would be reduced by roughly $50 million in 2017. CMS initially estimated savings at $330 million, however, the agency lowered its estimate after reviewing OPPS claims data for the first six months of CY 2016. In addition, the proposed estimate included lower Medicare Advantage (MA) payments. In the final CMS deleted estimated MA-related savings because the 2017 Medicare Advantage payment rates were set before Section 603 could be implemented. If CMS had finalized the proposed rule policy using this revised assumption, the agency would have estimated reduced Medicare Part B expenditures at $70 million in 2017.

2018: CMS estimated the change in 340B reimbursement at $1.6 billion or $700 million over the proposed rule estimate. CMS recognized calculating an estimate was difficult in part because OPPS claims did not indicate the drub being provided was purchased with a 340B discount and outpatient drugs covered under 340B were not publicly available. CMS noted the agency would implement the policy in a budget neutral manner, i.e., the agency would redistribute an equal dollar amount for non-drug items and services across the OPPS.

2019: Regarding the agency's HCPCS G0463-related policy, CMS estimated a decrease in OPPS payments at $300 million plus another $80 million in beneficiary copayments. Had CMS fully implemented the policy change in 2019, total Medicare and beneficiary copayments would have decreased by $750 million.

2020: In the proposed 2020 OPPS rule, CMS estimated the second-year phase in of the HCPCS G0463-related policy would save $810 million in 2020. Fully implemented, CMS estimates the policy will reduce OPPS payments by 1.2% or more.

Support for Site Neutral Payments

Section 603 enjoys considerable bi-partisan support. For example, in a March 1 American Enterprise Institute (AEI) - Brookings joint letter to HELP Committee Chairman, Lamar Alexander, recommending policies "to slow the rate of increase of health care costs, AEI and Brookings recommended site neutral payments apply to "all services delivered in HOPDs – both off and on-campus." AEI and Brookings also recommended the Congress eliminate Section 603's excepted or grandfathered HOPDs. In a 2018 publication Brookings argued site neutral also be expanded to include currently-exempt ambulatory surgical centers. The HELP Committee in later June passed Chairman Alexander's bill, titled the Lower Health Care Costs Act of 2019 (S. 1895). It is expected to pass the full Senate this fall.

Beyond providing savings to the Medicare program and its beneficiaries, MedPAC, AEI, Brookings, and, among others, the Center for American Progress, argue eliminating current payment differentials may contribute to market consolidation eroding provider competition and weakening an insurer's ability to have patients seek lower cost care. Eliminating the excepted or

grandfathered off-campus provision and the standalone emergency department exemption would also reduce the incentive for hospitals to add clinicians to their excepted outpatient departments and the incentive to build more emergency capacity. In its 2019 budget the Trump administration proposed removing these exceptions and estimated savings at $34 billion over ten years. CBO estimated the savings at $14 billion. Concerning on-campus outpatient departments, if they too received site neutral payments, per a 2017 MedPAC estimate, combined savings would equal $2 billion annually.

With bipartisan support it is not surprising in CMS' July 10 press release announcing a radiation oncology payment demonstration, the agency noted the mandatory episode-based payment demo involving physician group practices, HOPDs and freestanding radiation therapy centers would be site neutral. Less than two weeks later in July 22 speech CMS Administrator Seema Verma lamented the fact that "Medicare actually pays more for many services when they're performed in the hospital." This has led, she argued, to "surplus [hospital] beds," causing hospital spending to be "the largest driver of healthcare costs" and "what's worse," she stated, "is government [payment differential] policies are leading to the creation of monopolies, further thwarting competitive forces, resulting in an upward trend in provider consolidation."

Challenging Site Neutrality

The regulatory implementation of Section 603 exceeds the Congress's intent.

The 2019 Final Rule Is Illegal

The American Hospital Association (AHA), the Association of American Medical Colleges and others filed suit against Secretary Azar this past December challenging CMS' 2019 final OPPS rule that reduced excepted HOPD reimbursements for clinic visits or for HCPCS Code G0463 visits. The AHA and others argue the Medicare statute prohibits CMS from "selectively slashing the payment rates for specific types of services," i.e., year-over-year payment adjustments must be budget neutral. The plaintiffs also argue reducing excepted HOPD reimbursements violates the Congress's deliberate intent to create excepted and non-excepted (or grandfathered and non-grandfathered) HOPDs. That is excepted and non-excepted PBDs be treated differently. Concerning the Department's defense that it has the authority under Subsection (t)(2)(F) of the Social Security Act or that it is controlling for "unnecessary increases in volume for a specific service," the plaintiffs argue the comparative disparity in visits does not, per se, make them unnecessary in part since HOPD patients on average tend to be higher acuity and for this reason visits to HOPDs and freestanding physician offices are not (altogether) interchangeable.

For these reasons there is nascent support in the Congress. The Protecting Local Access to Care for Everyone Act of 2019 (HR 2552), would for payment years 2019 and 2020 restore OPPS clinic visit (HCPCS Code G0463) reimbursement rates for excepted HOPDs.

In Practice Site Neutrality Is Unsupported by the Evidence, Fails to Recognize Non-Comparable Patient Characteristics and Fails to Recognize and Reward Value

There is Little Evidence To Support Section 603

CMS, MedPAC and others provide no evidence payment differentials alone are causing unnecessary or excessive utilization, market consolidation, etc. For example, there is evidence, (published in the Journal of Health Economics in 2016) that hospital ownership of physician practices increases the probability physician patients will choose the owning hospital for follow up care. Whether or not increased probability translates to excessive utilization or comparatively worse outcomes is unknown. In addition, as Brookings noted in its 2018 paper, "site-of-service payment differentials are not the only factor driving hospitals to acquire physician practices." For example, it is highly likely if not in fact the case hospitals are simply responding to the migration of medical technology to the outpatient setting. For example, in the currently proposed OPPS rule, CMS is seeking comment on moving total hip arthroplasty (THA) for appropriately selected patients off the Inpatient Only List (IPO) and into the outpatient setting.

Section 603 Fails to Recognize or Account for Non-Comparable Characteristics

In making its March 2014 recommendation MedPAC admitted three problems with HOPD site neutral payments:

1. HOPDs comparatively care for higher acuity patients
2. they incur standby emergency capacity, and
3. incur higher overhead costs.

MedPAC however failed to address these concerns.

Concerning higher acuity patients, in April the American Hospital Association (AHA) released findings by KNG Health Consulting that found when compared to Ambulatory Surgical Centers ASCs), HOPD patients were more likely to be minorities, dual eligible, from lower income areas, suffer higher acuity or burdened with more severe chronic conditions and more likely to be previously hospitalized.

CMS has recognized and rewards providers with comparatively higher acuity patients. For example, in 2017 CMS initiated an effort to make MA's Star Ratings rewards program more equitable for MA plans providers who care for a comparatively greater number of Dual Eligible, Low Income Subsidy (LIS) and disabled beneficiaries. CMS implemented a Categorical Adjustment Index (CAI) that would add or subtract from a MA contract's Overall and/or Summary Star Rating to adjust for the average within-contract proportion of Dual Eligible, LIS and disabled beneficiaries.

Concerning higher overhead costs, MedPAC cannot reasonably argue higher fixed cost organizations be reimbursed the same as lower fixed costs organizations nor can CMS expect the former to remain in business under the latter's reimbursement.

Section 603 Ignores Spending Efficiency

In its March 2014 report MedPAC appropriately recognized site neutral payments do not differentiate or discriminate between high and low spending efficient providers. More recently, MedPAC stated in its March 2019 report, "Medicare's goal should be to obtain the greatest possible value [or spending efficient] for the program's expenditures." "Managing payment

rates," MedPAC wrote," alone will not address the Medicare FFS system's key challenge . . . [that providers] are usually not held accountable for outcomes." "The Congress and the Secretary . . . [must] move the Medicare program beyond just blindly paying FFS rates."

Site neutral payments epitomize "blindly paying FFS rates."

The Medicare program, in sum, neither measures nor rewards for value or again spending efficiency - defined as outcomes achieved relative to spending. For example, the Medicare Access and CHIP Reauthorization Act's (MACRA's) Merit-Based Incentive Payment System (MIPS) program measures for quality and cost separately, not simultaneously. The Medicare Shared Savings Program, CMS' flagship Alternative Payment Model (APM), also does not measure quality and spending simultaneously or attempt to correlate quality or outcomes achieved relative to spending. Neither do Part A's four incentive payment programs, including the Hospital Value Based Purchasing Program (VBP), nor the MA program.

Failure to do so has led to perverse effects. Currently, CMS financially rewards hospitals and physician practice groups that are spending efficient but achieve comparatively worse quality performance while financially punish providers with superior quality that are comparatively less spending efficient. Failure to account for spending efficiency also produces a reverse Robin Hood effect where CMS financially rewards providers at the expense of financially penalizing others with comparatively higher acuity patients.

As it relates to HOPDS, in early 2015 this, then potential, problem was identified by researchers in a study published by the Healthcare Financial Management Association. Titled, "Why Medicare Should Recognize the Value of Provider-Based Clinics," researchers identified high, mid and low-impact (read: spending efficient) on-campus and off-campus outpatient hospital care by using E&M claims data and readmission ratios for Acute Myocardial Infarction (AMI), pneumonia and heart failure. Using MedPAC's 2012 model estimating equalizing or site neutral payments, researchers concluded 186 high-impact hospitals, or 10% of 1,863 hospitals identified in the study, would bear 56%t of total payment reductions. Beyond accruing a disproportionate percent of the reduce payments, the researchers found the high impact hospitals also disproportionately treated indigent or underserved patients. The researchers concluded, "if the outpatient payment equalization policy [as modeled by MedPAC] were enacted, hospitals with a high percentage of uncompensated care would be disproportionately affected to could be forced to change their business model. Loss or shrinkage of hospital-based clinical networks could force patients back to safety-net inpatient care and emergency departments." That is, the policy would not only lead to disproportionately distributing payment cuts but also lead to a reverse Robin Hood effect.

Concerning resultant business model changes, in a recent Health Affairs essay, Mike Chernew and Richard Frank warned Medicare policymakers that they should carefully "titrate provider payment rates as their responses [to changes in payment policy] become more apparent." The authors supported this conclusion by noting data that showed increases in one-year AMI mortality after measurable changes in reimbursement. Previous cuts in Medicare reimbursement have shown, for example, that every $1,000 predicted loss in Medicare revenue per discharge was associated with a 2% increase in one-year mortality.

MedPAC has also argued for well over a decade that the Medicare program should reimburse providers based on beneficiary characteristics such as comorbidities, age and reason to treat. The Congress and CMS have been incrementally working toward this goal. For example, this was Congress's intent in passing in 2014 the bipartisan Improving Medicare Post-Acute Care Transformation (IMPACT) Act. IMPACT creates standardized assessments for care across the spectrum of four post-acute care providers (specifically home health, inpatient rehabilitation facilities long term care hospitals and skilled nursing facilities) that ensures patient care is delivered based on beneficiary characteristics and eliminates the current non-comparative, silo focused approach to quality performance benchmarking and reimbursement.

Similarly, the Senate HELP Committee's Lower Health Care Costs Act of 2019 (noted above) is designed, in part, to make transparent commercial payer-achieved care outcomes. Section 303 of the bill calls for a non-government, non-profit entity to publicly report commercial health care data concerning care delivery cost, quality and value or spending efficiency. Concerning CMS, in its just-published proposed Physician Fee Schedule rule the agency contemplates creating MIPS Value Pathways (MVPs) to "reward high value care." CMS states specifically in the proposed, "we define "value" as a measurement of quality as related to cost." Similarly, in the proposed OPPS rule's discussion of price transparency, CMS notes the agency's intent to "pair" quality of care and outcome data with price information "to allow patients to make informed decisions about where they could receive their care and to help ensure that consumers do not assume that the high cost of services necessarily equates to higher quality of care."

Conclusion

In implementing Section 603 CMS is effectively discriminating against excepted HOPDs thereby creating an unlevel playing field between them and freestanding physician offices. More substantively, differences in patient populations (that are recognized in other Medicare silos), differences in fixed or overhead costs, the failure to account for value or spending efficiency and the potential for unintended negative consequences, policy makers should reconsider or at least refine Section 603 to include rewarding value in provider payment policies. For example, since it appears HOPDs will be paid increasingly under the Physician Fee Schedule and since it is CMS' policy to incent providers to participate in APMs, HOPDs should be explicitly allowed to compete for MACRA's 5% Advanced APM bonus.