National Business Group on Health®

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

September 11, 2017

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

RE: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Changes for 2018, and Releases a Request for Information (CMS-1678-P)

Dear Administrator Verma:

On behalf of approximately 415 primarily large employers, including 73 of the Fortune 100, who voluntarily provide group health plan coverage and other health programs to over 55 million American employees, retirees and their families, The National Business Group on Health appreciates the opportunity to comment on CMS' proposed OPPS changes for acute care hospitals for 2018. We applaud your leadership and that of the Secretary in continuing to transform traditional Medicare away from fee-for-service reimbursement toward alternative payment models that command value and efficiency.

In its final rule, we support CMS' efforts to:

- ***Modify the Medicare inpatient-only list (IPO)***. Medical innovation has evolved to an extent that now permits some previously IPO procedures to be performed using less-invasive and less-involved surgical protocol. Moreover, they can be done safely and of equal or better quality in outpatient settings, for many patients. Specifically, we support CMS' effort to continuously evaluate procedures that can be considered for removal from the IPO and in the case of the proposed rule, remove total knee arthroplasty (TKA) from the IPO list.
- ***Remove six measures from the Hospital Outpatient Quality Reporting (OQR) Program***. This will result in a burden reduction of 152,680 hours and $5.6 million for the CY 2020 payment determination and 304,810 hours and $11.1 million for the CY 2021 payment determination[1]. Additionally, removing reporting on measures that are "topped out" allows for a payment determination that is more reflective of realistic performance benchmarks and one that better determines when an appropriate threshold of provider performance has been reached in a variety of group practices.

[1] Centers for Medicare and Medicaid Services, Proposed Rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. Published in the Federal Registrar at https://www.federalregister.gov/documents/2017/07/20/2017-14883/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. Accessed August 31, 2017.

- ***Add three procedure-type specific measures to the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.*** These additional measures will provide patients with more valuable ASC performance data and address the clinical areas that are critical to providers. Specifically, we support the addition of the three quality measures noted in the proposal:
    - ASC-16: Toxic Anterior Segment Syndrome (TASS) measure;
    - ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and
    - ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.
- ***Remove three ASCQR Program measures for the CY 2019 payment determination and subsequent years.*** Removal of these measures would alleviate maintenance costs and administrative burdens to the ASCs, resulting in a burden reduction of 1,314 hours and $48,066 for the CY 2019 payment determination.[2]
- ***Extend the moratorium regarding supervision of OP therapeutic services.*** Hospital outpatient therapeutic services have always been provided by licensed, skilled professionals under the overall direction of a physician and with the assurance of rapid assistance from a team of caregivers, including a physician, should an unforeseen event occur. Additional supervision requirements may be both burdensome and unnecessarily duplicative.
- ***Modify packaging policies to improve patient care.*** By adding a new HCPCS code for certain procedures that utilize a drug which would otherwise be packaged, and adding a "complexity adjustment" to the pairs of codes (the procedure code and the new packaged drug code) to increase reimbursement and account for the dilution of the drug reimbursement in the procedure payment, CMS is showing flexibility to adjust programs while continuing to advance payment policies that promote improved care and efficiency.

In its final rule, we specifically urge CMS to:

- ***Reconsider substantive comment on key elements of its interpretation of the site-neutral rule.*** Substantive clarification is needed on service line expansion and volume at off-campus provider-based departments excepted from OPPS reimbursement. Specifically, we encourage the agency to revive last year's proposal for inclusion in this year's final rule, to establish a subset of "clinical families" of services. However, we support the Agency's concurrent proposal to reduce CY 2018 payments to off-campus hospital outpatient departments (HOPDs) subject to the site-neutral rule, implemented as part of the Balanced Budget Act (BBA).[3]
- ***Refine its proposal regarding payment for drugs and biologicals purchased with a 340B program discount.*** While we have operational concerns with the 340B program and believe it may inflate prescription drug pricing, the proposal as written does not reform any of the problematic components of the program and an across-the-board cut in reimbursement may actually exacerbate programmatic challenges. Generally, the 340B program should be reformed to better define the patients it is serving and do more to assure that the program benefits are going to the indigent and that the program is not being misused or generating unintended profits for any stakeholders within the program. We make additional specific recommendations in the addendum.
- ***Implement the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) under the ASCQR Program for CY 2018 data collection***.

[2] Ibid.

[3] Centers for Medicare and Medicaid Services, Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. Published in the Federal Registrar at https://www.gpo.gov/fdsys/pkg/FR-2017-07-21/pdf/2017-14639.pdf. Accessed August 31, 2017.

These consumer assessments uncover areas of care not adequately addressed within existing measure sets and will be useful to assess aspects of care where the patient is the best or only source of information. Additionally, patient satisfaction and patient experience of care are important aspects of assessment of provider performance and quality of care.

In the following addendum, we provide expanded comments on key items.

What Medicare does to improve efficiency and quality will have a valuable spillover effect for our health care delivery system, the health of the population and the nation's economy. We look forward to continuing to work with you to transition our nation's health care system to one based on value, quality and health improvement. Again, thank you for the opportunity to comment. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO

Addendum

Clarify key elements of the site-neutral rule

We were pleased that CMS proposed limitations on service line expansion and volume at off-campus provider-based departments excepted from OPPS reimbursement in the 2017 OOPS rule, but disappointed when that part of the proposal was not finalized; We are further disappointed that CMS is not making any similar proposals or clarifications for CY 2018 and urge the agency to reconsider this important inclusion. Through Section 603 of the BBA, Congress sought to focus payments on services, rather than the setting. As the agency well knows, the race for vertical integration in the hospital and provider communities has led to an increase of disproportionate reimbursement rates at off-campus HOPDs, which has not been linked to an increase in resources expended for same services, or an overall improvement in quality of patient care.

We encourage the agency to revive last year's proposal for inclusion in this year's final rule, to establish a subset of "clinical families" of services. Last year's proposal sought to establish the distinction, that only excepted HOPDs billing within one of those 18 clinical families prior to the enactment of the BBA would be eligible for reimbursement under the OPPS on a going-forward basis. In our comments, we strongly supported this proposed policy.

Through the establishment of clinical families, as proposed last year, we understood that CMS sought to enforce equitable reimbursement for "expected items and services" provided by provider-based departments, on the basis of whether or not they are truly providing hospital-based services. To the extent that an HOPD is providing care that is not considered hospital-based, but is being reimbursed at higher levels simply by virtue of consolidation, and not because that care is linked to proportionately improved outcomes, we welcome this important clarification by the agency and encourage its inclusion in this year's final rule.

The Medicare Payment Advisory Commission (MedPAC) has reported on disparate reimbursement payments within the Medicare population. For example:

- Medicare reimburses $453 for a level II echocardiogram performed in an off-campus HOPD vs. $189 in a doctor's office
- Similarly, Medicare reimburses $1,383 for a colonoscopy performed in an off-campus HOPD vs. $625 in a doctor's office

Employers are increasingly aware of a wide variation in site-of-service billing practices facing their employees at off-campus HOPDs. While transparency tools are being made available to employees to facilitate medical shopping and encourage cost-consciousness, these efforts alone are not enough as employers search for ways to control their health benefit expenses and keep costs affordable for employees. This payment differential has encouraged hospitals to acquire physician practices in order to receive the higher rates. This difference in payment also increases costs for the Medicare program and raises the cost-sharing liability for beneficiaries.

With that in mind, we also encourage CMS to work with the Congress to eliminate the grandfathering of arrangements in existence prior to enactment of the BBA. Left intact, these arrangements will inhibit the growth of cost effective and innovative payment and delivery systems, such as Accountable Care Organizations (ACOs) and other alternative payment models. At a minimum, we would encourage

CMS to work with the Congress to develop a scheduled phase out of these existing arrangements over a reasonable time period. Allowing existing arrangements to be grandfathered 1) raises questions of fairness, 2) could provide regulatory protection from competition for the grandfathered entities and 3) could inhibit the growth of lower cost alternatives in the affected areas.

340B program discount

While we have operational concerns with the 340B program and believe it may inflate prescription drug pricing, the proposal as written does not reform any of the problematic components of the program and an across-the-board cut in reimbursement may actually exacerbate programmatic challenges. Generally, the 340B program should be reformed better define the patients it is serving and do more to assure that the program benefits are going to the indigent and that the program is not being misused or generating unintended profits for any stakeholders within the program. Below, we make additional specific recommendations.

340B Contract Pharmacies

The growth of 340B contract pharmacies has raised concern for employers, other third party payers, and pharmacy benefit managers. ***However, we don't agree that a flat cut to hospitals participating in the 340B program from a current rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent would present any programmatic solutions for the challenges that plague the program***. We understand that the cut put forth in the proposed rule is based on MedPAC's conclusion that, on average, hospitals in the 340B program receive a minimum discount of 22.5 percent of ASP for drugs paid under the OPPS.

However, the 340B program also enables safety-net providers to stretch limited resources, reach more eligible patients and provide more comprehensive services. Entities that acquire drugs at 340B prices rely on the savings to remain solvent and to expand healthcare services to vulnerable populations, including by reducing or waiving patient co-pays for Part D drugs.

Given these two conflicting facts (operational concerns and growth, combined with the good intent of the program), we think that CMS would do better to strive to achieve both programmatic savings and needed reform by focusing on specific flaws within the program, relative to contract pharmacies, including 1) formulary rebates, 2) profits from managed care paid prescriptions, 3) challenges for managed care from 340B contract pharmacies, and 4) the disruption of managed care pharmacy networks.[4] Each of these areas, if reformed, could have the impact of either reducing the net prices of prescription drugs in the 340B program, or slowing the overall growth of prescription drugs within the program.[5]

Expansion to Hospitals and Communities Serving More Insured Patients

In addition to concerns with contract pharmacies, the excerpts below are from a 2014 Health Affairs study, which suggests that the 340B program is being converted from one that serves vulnerable communities to one that enriches participating hospitals and the clinics affiliated with them:[6]

[4] Adam J. Fein, "Challenges for Managed Care from 340B Contract Pharmacies," *Journal of Managed Care & Specialty Pharmacy* 22, no. 3 (February 22, 2016): 197–203, doi:10.18553/jmcp.2016.22.3.197.
[5] Ibid.
[6] Rena M. Conti and Peter B. Bach, "The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities," *Health Affairs* 33, 10 (2014):1786-1792 doi: 10.1377/hlthaff.2014.0540 (n.d.).

- Beginning around 2004, newly registered 340B DSH hospitals have tended to be in higher-income communities, compared to hospitals that joined the 340B program earlier.
- Affiliated clinics tended to serve communities with lower poverty rates and higher mean and median income levels than their 340B DSH hospital parents did.
- Expansions among 340B DSH hospitals run counter to the program's original intention.

The Health Affairs study suggests that "an important future empirical analysis would examine whether 340B DSH hospitals are pursuing such activities at a different rate, are targeting different patient populations, or both, compared to hospitals that do not participate in the 340B program."[7] The study goes on to suggest that 340B drug discounts may act as a motivating rationale for vertical integration among hospitals and outpatient physician practices.[8]

In sum, CMS should 1) work with employers and other third party payers to better understand how the 340B program impacts the private market by developing objective, transparent research on the 340B program's costs, benefits, and implications for managed care pharmacy and practice; 2) conduct an evaluation of the program's reach that would inform the agency on whether or not the program is being targeted to communities of underserved populations, as originally intended; and 3) perform analyses to understand whether the 340B program is a motivating factor in the rapid vertical integration of hospitals and outpatient physician practices.

Implement the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS)

These consumer assessments uncover areas of care not adequately addressed current measure sets and will be useful to assess aspects of care where the patient is the best or only source of information. Additionally, patient satisfaction and patient experience of care are important aspects of assessment of provider performance, and quality of care. CMS has previously noted that there is currently no standardized data available on the patient experience following outpatient surgeries or procedures, and that OAS CAHPS supports the agency's efforts to better capture patient-centered assessments. Hospital participation in the OAS CAHPS should be mandatory beginning in 2018, which is slated under current law. The OAS CAHPS has the potential to identify areas for improvement through comparison of patient responses against state and national averages. The ability to make these meaningful comparisons runs in congruence with the agency's overall aim to improve care alongside patient satisfaction, which is also a key priority for employers.

Remove measures from the Hospital Outpatient Quality Reporting (OQR) Program

We support efforts to continue the emphasis of the Hospital OQR Program on quality reporting for hospital inpatient services focused on measures that have high impact and support national priorities for improved quality and efficiency of care, as well as on conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To that end***, we strongly support the removal of quality measures that have been shown to be "topped-out."*** In addition to the reduction in time and monetary burden associated with reporting on the chart abstracted measures proposed for removal, we specifically support removing:

[7] Ibid.
[8] Ibid.

OP-21: Median Time to Pain Management for Long Bone Fracture, which measures the median time from emergency department (ED arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture. This measure is proposed to be removed beginning with the CY 2020 payment determination.

We have concerns that any link between scoring well on pain management and higher hospital payments may create perverse incentives to overprescribe opioids. Because some hospitals have identified patient experience as a potential source of competitive advantage, we agree that there is a legitimate concern that how a hospital rates on pain management may unduly impact its overall HCAHPS Survey scores.

We look forward to CMS's additional guidance on this issue, and also look forward to working with the agency and other appropriate authorities on this important public health crisis.

Removal of Total Knee Arthroplasty (TKA) Procedure from the Inpatient Only (IPO) List

We agree that total knee arthroplasty (TKA) or total knee replacement, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)), which has traditionally been considered an inpatient surgical procedure, could now be performed on an outpatient basis without negative impacts on outcomes or quality. We additionally support the removal of partial and total hip arthroplasty from the IPO list.

When the TKA procedure was initially listed as IPO, it was considered highly invasive and required at least 24 hours of post-operative care. Since 2000, as CMS points out, the average hospital stay for this procedure has been reduces from 4.6 days in 2000, to 2.8 days in 2016, due in large part to medical innovation. With advances in minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols, we feel that it's imperative to minimize unnecessary inpatient hospitalizations that could expose patients to a host of hospital-acquired conditions and infections.

While we understand certain patients will require inpatient admission for TKA procedures, absence from the IPO list does not preclude the procedure from being performed on an inpatient basis. However, IPO listed procedures must be performed on an inpatient basis in order to qualify for Medicare payment, which removes provider flexibility in determining the best course of treatment for a patient. Given that IPO list status of a procedure has no effect on the Medicare Physician Fee Schedule (MPFS) professional payment for the procedure, it makes sense to remove the TKA from being listed as an IPO procedure.