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-1676-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2018 (CMS-1676-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 updates to the Medicare Physician Fee Schedule for Calendar Year 2018. In this proposed rule, we are pleased to see CMS' focus on neutralizing payment rates for same services at different health care sites, reducing reporting burden on providers, as well as focusing on the nation's opioid and behavioral health epidemics. Additionally, 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:

- 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);
- Add services to the covered telehealth list for Medicare patients;
- Improve payment rates for office-based behavioral health services;
- Establish a multi-year effort to revise the Evaluation and Management Guidelines;;
- Add two new billing codes that would be exclusive to RHCs and FQHCs and in addition to payment for an RHC or FQHC visit; and
- Align reporting under the Physician Quality Reporting System (PQRS) with MIPS.

In its final rule, we specifically urge CMS to:

- Reconsider reduction automatic downward payment adjustment from -4 percent to -2 percent for groups with ten or more clinicians, and from -2 percent to -1 percent for solo practitioners or groups with less than nine clinicians. By reducing the value modifier, CMS is sending mixed signals to providers about its commitment to the implementation of the QPP under MIPS. It also weakens the resolve of providers who were diligent about putting in place systems and protocol that would allow them to succeed under the program. We urge CMS to stick to current law with regard to the 2018 value modifier.

In the following addendum, we provide expanded comments on key items, as well as thoughts on the requests for information related to biosimilar payment policies and treatment of opioid use disorder.

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

2018 Value Modifier

MIPS addresses providers' longstanding complaints that reporting under the existing programs—the Physician Quality Reporting System, the Value-Based Modifier, and Meaningful Use — is duplicative and cumbersome. Additionally, MIPS proposes to make positive or negative adjustments to a physician's payment based on his performance.

CMS is proposing a number of changes to those policies. These include reducing the automatic downward payment adjustment from -4 percent to -2 percent for groups with ten or more clinicians, and from -2 percent to -1 percent for solo practitioners or groups with less than nine clinicians. In addition, CMS has proposed to hold harmless from downward payment adjustments those physician groups and solo practitioners who met minimum quality reporting requirements for the last year of the Quality Payment Program (QPP).

We have concerns about delaying or reducing the value modifier, which was put in place to incent providers to report quality data under the QPP.

The Business Group has consistently supported CMS's efforts to reform and refine payment policies focused on rewarding value, performance and quality, especially including those outlined within MACRA, the hospital quality improvement program, and the move to alternative payment models. CMS's efforts complement that of many large employers who are working either directly with providers or with their commercial health plan partners to implement alternative payment and delivery models such as ACOs, patient-centered medical homes (PCMHs) and bundled payments for their employees because of their potential to improve health care quality, value and efficiency.[1]

Simultaneously, we have also supported reduced reporting burden for providers, where that reduced burden does not slow the transition away from FFS. ***However, by reducing the value modifier, CMS is sending mixed signals to providers about its commitment to the implementation of the QPP under MIPS. It also weakens the resolve of providers who were diligent about putting in place systems and protocol that would allow them to succeed under the program. We urge CMS to stick to current law with regard to the 2018 value modifier.***

Non-Excepted Off-Campus Provider-Based Hospital Department Payment Reductions

Section 603 of the BBA sought to impose a "site-neutral" payment policy for new off-campus PBD locations, also known at HOPDs, established on or after November 2, 2015. Medicare has historically reimbursed services provided at HOPDs at a higher rate as compared to freestanding facilities and practices as a result of the ability to bill for a facility fee reimbursed under the OPPS in addition to professional services reimbursed under the MPFS. Section 603 worked to neutralize this additional reimbursement for HOPDs, excluding dedicated emergency

[1] National Business Group on Health. Large employers' 2015 health plan design survey. 2014. https://www.businessgrouphealth.org/pub/b4c900ee-782b-cb6e-2763-0aa2f9563309

departments. Under Section 603, HOPDs billing for services under OPPS furnished prior to November 2, 2015, have "excepted" status and are not subject to the site-neutral payment rule, unless they undergo an impermissible change of ownership or relocation.

We supported the neutralization of payment rates for off-campus PBDs, as we believe that same or similar healthcare services, whether provided in a HOPD or a free-standing provider office, should be reimbursed at same or similar rates.

Through the Medicare Payment Advisory Commission (MedPAC), we know disparate reimbursement payments exist 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 have become aware of a wide variation in site-of-service billing practices 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. 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.

The 50 percent rate in CY 2017 was intended to be a transitional policy until more precise data could identify and value such non-excepted items and services furnished by non-excepted HOPDs. ***We support CMS' methodology in determining the reduction to 25 percent rate by comparing the OPPS payment rate for HCPCS code G0463, or clinic visit, to the difference between the non-facility and facility PFS payment amounts using CY 2017 rates for the weighted average of outpatient visits billed by physicians and other professionals in an outpatient hospital place of service. This methodology seeks to determine a fair and equitable reimbursement across facility types, for same or similar services, thereby leveling the playing field for payers and patients.***

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 a regulatory protection from competition for the grandfathered entities and 3) could inhibit the growth of lower cost

alternatives in the affected areas.

Additional Telehealth Services

There is a growing body of evidence to suggest that utilization of telehealth can both reduce health care costs and increase access to specialty and routine health care services. Thus, as medical technology continues to advance, providers and health care systems are increasingly incorporating telehealth into health care delivery. Concurrently, employers are embracing telehealth services by adding them to the menu of health benefits provided to employees. According to the Large Employers' 2018 Health Care Strategy and Plan Design Survey, virtually all employers (96%) will make telehealth services available in states where it is allowed next year. More than half (56%) plan to offer telehealth for behavioral health services, which is more than double the percentage this year. Telehealth utilization is on the rise, with nearly 20% of employers experiencing employee utilization rates of 8% or higher.[2]

Federal health care programs often influence commercial plan design and program benefits offered by private insurers. ***Utilization of telehealth services by Medicare, Medicaid and the Department of Veterans Affairs inform broader efforts within the health care system, and we support CMS' proposal to add additional services to the covered telehealth services list.***

Additionally we support CMS' proposal to eliminate the telehealth modifier GT, which has the descriptor "via interactive audio and video telecommunications system," on professional claims. Since Place of Service (POS) code 02 indicates both provision of telehealth services as well as certification that telehealth requirements have been met, the GT modifier is arguably unnecessary.

We believe there are sufficient guardrails in place to assure the legitimacy and quality of a telehealth visit. Telehealth services must either be similar to a professional consultation, office visit or office psychiatric service currently on the telehealth list, or provide a demonstrable clinical benefit. Additionally, CMS already requires that:

- The procedure must be furnished via an interactive telecommunications system.
- The procedure must be furnished by a physician or an authorized practitioner.
- The procedure must be furnished to an eligible telehealth individual.
- The recipient must be in a telehealth originating site.

[2] The Large Employers' 2018 Health Care Strategy and Plan Design Survey was conducted between May and June 2017. A total of 148 large employers participated in the survey. Collectively, respondents represent a wide range of industry sectors and offer coverage to more than 15 million employees and their dependents. Two-thirds of respondents belong to the Fortune 500 and/or the Global Fortune 500, and 42 belong to the Fortune 100. The survey can be accessed here: https://www.businessgrouphealth.org/pub/?id=62A23B83-DC87-F58C-38FB-881AF80C8272

Thus, and consistent with our previous comments, we support efforts to streamline barriers to telehealth utilization, as well as encourage and increase telehealth utilization as a safe and effective alternate access point for health care services.

Improvement of Payment Rates for Office-Based Behavioral Health Services

Across the health care system, treatment of mental health conditions has traditionally taken a back seat to physical health. The same is true for emotional well-being; for years, wellness programs have focused on behaviors like healthy eating, exercise and smoking cessation, and less so on improving the emotional state of the employee. But in recent years, mental health and emotional well-being have become increasingly important to health care providers, employers, health plans and, of course, employees.

There are several reasons why these two areas are now of greater concern to employers:

- The scope and impact of mental health conditions on worker productivity and costs are clearer.
- The opioid epidemic has thrust issues related to addiction into the national spotlight.
- Younger generations who have grown up with social media might be more willing to talk publicly about mental health conditions and emotional well- being issues.
- Payment and delivery reforms have put a greater onus on health care providers to improve health outcomes and reduce costs, which cannot be done without improving access to treatment for mental health services.
- Employers increasingly understand that the value-proposition for workers to remain at their company includes benefits like social connectedness, financial security and emotional health.

Inadequate provider networks have historically contributed to limited access for plan members, related to finding services for behavioral health. In many cases, plan members are unable to find in-network mental health care professionals who are accepting new patients, or they are forced to wait for months or travel long distances to see a professional when they need help the most. Patients in need of care often go out-of-network to access providers, which is expensive to the member and the plan, may require onerous travel (reducing productivity) and side-steps quality requirements that the plan may place on in-network providers. Sadly, some patients are taken advantage of by fraudulent out-of-network providers who offer to pay the patient's cost-share and submit large claims, but then fail to adequately treat the patient.

We applaud CMS' recognition through the proposed rule that office-based behavioral health services, and appropriate payments to compensate for the overhead expenses associated with those services, are critical to improving overall patient and societal health. As is often the case, policies implemented by CMS may have the ability to impact the private market. ***Recognizing the great value in adequate behavioral health services, we strongly support realignment of payment policies that encourage adequate reimbursement for these services, thus increasing patient access.***

Evaluation and Management (E/M)

We are pleased to see that CMS is evaluating current reimbursement policy requiring that billing practitioners bill patient visits to the PFS by maintaining information in the medical record to document that they have reported the appropriate level of E/M visit code. Specifically, we applaud CMS' effort to take a long-term look at how to revise E/M codes and payment policies and agree with the Agency that, in general, the current requirements may be an unnecessary burden and that they are potentially outdated, and believe this is especially true for the requirements for the history and the physical exam. Moreover, since the guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, there are challenges for data and program integrity and the potential for upcoding, given the frequently automated selection of code level.

Revised guidelines based on a multi-year, collaborative effort among stakeholders could both reduce clinical burden and improve documentation in a way that would be more effective in clinical workflows and care coordination. Further, we agree that medical decision-making and time are the more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties. ***However, since evaluation and management are a major part of primary care, and essential to proper diagnosis of illness, appropriate chronic care management, and determination of treatment, we support efforts to assure that these are appropriately valued for general and family practitioners and other clinicians providing primary care***

We look forward to following the Agency's work on this issue.

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

As mentioned above, addressing challenges and barriers to effective, evidence-based care for complex chronic care management, behavioral health integration and psychiatric collaborative care must be a strategic priority for both public and private payment models. Patients living in rural areas are often hit the hardest by narrow networks, unable to find in-network care professionals who are accepting new patients. They are either forced to pay exorbitant out-of-network fees, or they are forced to wait for months or travel long distances to see a professional when they need help the most.

Thus, we are pleased to see that CMS has recognized that this is a particular disparity for those living in rural communities, by proposing to add two new billing codes that would be exclusive to RHCs and FQHCs and in addition to payment for an RHC or FQHC visit. These codes will be a welcome additional to both patients living in these areas, as well as the providers servicing them. Further, these additional payments would encourage complex chronic care management, behavioral health integration, and psychiatric collaborative care models.

Medicare Shared Savings Program Rules

The Medicare Shared Savings Program (MSSP) allows providers to organize into ACOs to continue to receive FFS payments for services furnished to Medicare beneficiaries. Such ACOs are eligible for additional payments if the ACO achieves certain quality and cost savings benchmarks and, in some ACO models, provides also are responsible for some portion of the budget overruns.

We strongly support market transitions away from FFS payment arrangements to those which place a focus on value-based payments, particularly accountable care arrangements that encourage care coordination and provider accountability for population health and believe that CMS should: 1) maintain high performance standards for quality and efficiency for ACOs; 2) reward ACOs that accept full responsibility and accountability for effective and efficient care; and 3) avoid adverse competitive impacts through unwarranted higher costs or cost-shifting to others.

While we believe that CMS should set high standards for ACOs and continuously monitor and evaluate ACO performance, to ensure that they are increasing care coordination and lowering health care costs, we also support efforts by CMS to make ACOs an attractive and viable solution for providers, particularly those in rural communities. ***Specifically, we support CMS' efforts within the proposal to:***

- ***Revise the methodology for assigning beneficiaries to ACOs to treat services reported on RHC or FQHC institutional claims as primary care services furnished by a primary care physician, which will reduce the reporting burden for RHCs and FQHCs; and,***
- ***Include three new chronic care management codes and behavioral health integration codes to the definition of primary care services in the ACO assignment methodology, which would allow for a complexity adjustment based on the time spent furnishing services for RHCs and FQHCs.***

These modifications may reduce unwillingness by rural providers to participate in ACOs by introducing payment policies that seek to eliminate perceived penalties associated with practicing in those areas.

Solicitation of Comments

A single average sale price payment policy for biosimilar products

We strongly support a regulatory environment which favors the robust uptake of high quality, safe, and efficacious biosimilars. We know that the availability of generic drugs has reduced drug prices and increased patient access to medicines, and we believe that competition among biosimilars may be able to do the same, as biosimilars competing for market share with each other, could be expected to lead to lower prices, as well as potentially greater access to these products.

However, current CMS policy, assigns a single billing code and payment rate to all biosimilars to a given reference product. We appreciate that CMS is taking a step forward toward reversing this policy by soliciting "new or updated information on the effects of the current biosimilar payment policy." We believe that action must be taken during this rulemaking to ensure that the biosimilars market is allowed to develop.

We strongly encourage CMS to reverse their position on biosimilar reimbursement as soon as possible in the context of the final rule, redrafting the relevant language to assign to each biosimilar a separate and distinct billing and reimbursement code.

Incentivizing organizations and professionals to treat opioid and other substance use disorders

A recent study of employer claims databases found[3]:

- Nearly one out of every three (32 percent) opioid prescriptions, which are subsidized by America's employers, is being abused.
- On average, 4.5 percent of individuals in the United States who have received a prescription for narcotic painkillers are opioid abusers. These individuals account for nearly one-third (32 percent) of total opioid prescriptions and 40 percent of opioid prescription spending.
- Opioid abusers cost employers nearly twice as much ($19,450) in medical expenses on average annually as non-abusers ($10,853).

Additionally, national data from the American Society of Addiction Medicine estimates that employers are losing $10 billion a year from absenteeism and lost productivity due to opioid abuse, and opioids make up one-quarter of all workers' compensation prescription drug costs.

Given the aforementioned direct costs associated with opioid addiction, and the substantial indirect costs to both employers and employees, the Business Group and our members are supportive of efforts to make access to treatment more readily available. Last year, we supported efforts to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA) from 100 to 200. We believe removing undue regulatory burden which limits the ability of qualified physicians to treat patients with opioid addiction is appropriate. We would additionally encourage HHS to consider 1) changes in the qualifications for a higher patient limit, including expanding the scope of practice for other qualified clinicians, such as nurse practitioners, to treat patients with opioid use disorder.

We believe that medication assisted treatment (MAT), which has been shown to be very

[3] "New Study Reveals 32 Percent of Total Opioid Prescriptions Are Being Abused," Castlight Health, April 20, 2016, http://www.castlighthealth.com/press-releases/new-study-reveals-32-percent-of-total-opioid-prescriptions-are-being-abused/.

effective in treating opioid use disorder[4], could be more thoroughly explored by CMS. As the agency considers ways to encourage practitioners to play a larger role in treating opioid use disorder, we encourage CMS to review a September 2014 SAMHSA meeting, in partnership with the National Institute on Drug Abuse. The meeting convened expert professionals for a Buprenorphine Summit to gather their perspectives on what is known about the adoption of MAT with buprenorphine-containing products to treat opioid use disorder; reasons why it has not been as widely prescribed as might have been expected; and ways that Federal agencies, health professionals, and concerned individuals might enable buprenorphine treatment to become more accessible.

Participants from the Summit provided specific reasons practitioners were not prescribing buprenorphine, including but not limited to the following:

1. Practitioners do not have practice partners with waivers or practice partners who can provide cross-coverage because of the interpretation of the patient limit;
2. they lack institutional support;
3. their community lacks psychosocial resources for patients;
4. they feel that with current patient limits, they cannot treat a sufficient volume of patients to meet all of the costs of providing buprenorphine given current third-party reimbursement;
5. the regulations and scrutiny particular to prescribing buprenorphine can make them feel as if they are doing something questionable by prescribing it; and
6. current confidentiality rules make it difficult to integrate substance use disorder care with primary care.

Some of the ideas that came out of the Summit included strategies to expand availability of buprenorphine treatment for opioid use disorders, such as examining the elimination of restrictions on prescribing buprenorphine. Specific ideas included:

1. enabling non-physician practitioners to prescribe buprenorphine (which would require a legislative change);
2. raising the cap on how many patients a practitioner can have in treatment at a time; and
3. allowing practitioners to cross-cover one another on a short-term basis, which is a practice standard across medicine, without being in violation of the patient limit.

While CMS has already begun to engage on some of the initiatives above, there is room for focus on other items highlighted at the SAMHSA meeting.

[4] Substance Abuse and Mental Health Services Administration. “Medication Assisted Treatment for Opioid Addiction: Facts for Friends and Family.” HHS Publication No. (SMA) 09-4443. 2011