September 10, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd.  
Baltimore, MD 21244

Submitted electronically at: regulations.gov

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

Community Catalyst respectfully submits the following comments regarding the proposed Medicare Physician Fee Schedule for CY 2019.

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1998, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. The Center for Consumer Engagement in Health Innovation focuses on health system transformation and bringing the consumer experience to the forefront of health. The Center works directly with consumer advocates to increase the skills and power they have to establish an effective voice at all levels of the health care system. We collaborate with innovative health plans, hospitals and providers to incorporate the consumer experience into the design of their systems of care. We work with state and federal policymakers to spur change that makes the health system more responsive to consumers, particularly those that are most vulnerable.

The Physician Fee Schedule rule provides an important opportunity to ensure that Medicare payments accurately reflect the time and effort needed to appropriately care for beneficiaries, and provide them with the services necessary to improve health outcomes or maintain quality of life. This rule is especially important from a consumer perspective, as it impacts what kinds of services Medicare beneficiaries receive, how much time their providers spend with them, and their out of pocket costs, among other things. With that perspective in mind, we appreciate the opportunity to provide comments on several provisions we think are particularly important to consumers.
Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

- **Brief communication technology-based services:** We are supportive of CMS’s efforts to modernize the PFS to recognize the different ways care is delivered and the role technology can play in providing more efficient and high value care. Virtual check-ins that can help assess whether or not a patient needs an office visit are beneficial to both beneficiaries, as well as providers and practices. They can help avoid unnecessary office visits, saving providers time and preventing patients from making an unnecessary trip to the provider’s office. This is especially important for beneficiaries with limited transportation access, mobility difficulties, or who live in rural areas and have to travel long distances. Recognizing the added importance of access to telehealth services for vulnerable populations and people living in rural areas, we are also supportive of CMS’s proposals that would allow Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to also bill for these services.

While we are supportive of the concept of virtual check-ins, we are concerned about costs being passed on to beneficiaries. For low-income Medicare beneficiaries, even a small co-pay can impact their financial wellbeing and whether or not they seek care. It may be confusing to beneficiaries to be billed for phone calls, particularly as this will be a new service. We suggest that virtual check-ins not be subject to cost-sharing. If cost-sharing is nonetheless imposed, we ask CMS to mitigate the impact on consumers in several ways: (1) implement the benefit without cost-sharing for an introductory period of several years, during which patients are educated about the benefit and the cost; (2) study the impact of this benefit on utilization and total out of pocket costs for consumers, and consumer acceptability; and (3) when cost sharing is implemented, require providers to inform patients of any associated cost sharing, as well as alternatives, and get verbal consent from patients before continuing with the visit. Additionally, we ask that CMS develop patient-friendly, linguistically accessible education materials explaining the new service and associated cost sharing that practices who choose to offer virtual check-ins should share with their patients.

- **Interprofessional Internet Consultation:** We support CMS’s efforts over the past few years to ensure that the PFS more adequately reflects the resources needed to treat complex patients and keeps pace with the shift in care delivery from an episodic treatment-based approach to a patient-centered care management approach. Peer-to-peer consultation can be helpful for obtaining appropriate specialty input in a way that is effective and efficient.

However, if not implemented carefully, it could also carry risks to patients, including increasing their out-of-pocket costs and impairing their ability to get their concerns and questions fully addressed through specialty consultation. Because these services are provided outside of the presence of the patient, ensuring these consultations are done for the benefit of the patient rather than the provider is difficult, and from an integrity standpoint, it may be challenging for patients to know what services are being billed in their name.

We are nonetheless supportive of the move to incorporate interprofessional consultation, and would like to see it implemented with the following safeguards: (1) no cost-sharing to beneficiaries; (2) patients should consent to internet interprofessional consultation, including
risks, benefits, and alternatives; (3) patients should have the ability to submit questions for the consultant specialist to address, to review the information being sent to the consultant, and to review the response of the consultant.

**Evaluation & Management (E/M) Visits**

E/M services can run the gamut from a focused, brief visit (such as for a urinary tract infection in an otherwise healthy patient), to a complex, over-hour-long visit (such as to review a patient’s 20+ medications, address multiple medical problems, review test results, discuss interval history and hospitalizations, and navigate a challenging home and social situation). This proposal would collapse E/M codes 2-5 into a single category. Reimbursing providers the same amount for services that are so different is flawed and unfair to providers who care for those patients with complex health and social needs, who need extra time and attention to get the care they need.

While we appreciate the desire to simplify coding requirements, we are deeply concerned about the impact of this proposed change on consumers, particularly those with the most complex care needs. Collapsing the codes could incentivize practices to increase the number of short patient visits and decrease the number of longer patient visits. This would mean that many patients might not receive the time and attention they need from their provider to fully address their health concerns, or that they might have to book multiple appointments in order to fully address a single concern. This would be incredibly burdensome, as it would increase the amount a patient is spending out-of-pocket to address their health care needs and is also difficult for patients who have transportation difficulties or need to take time away from work or caregiving responsibilities to get to an appointment.

We ask that CMS not move forward with the single payment proposal and instead work with stakeholders on an alternative that adequately compensates for services provided to complex patients and reduces the need for extensive documentation.

**Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments**

We support CMS’s proposed rule to reduce the Whole Acquisition Cost (WAC)\(^1\) add-on percentage from six percent to three percent for Medicare Part B Drugs. This change would ensure that the program does not over-reimburse for prescription drugs that lack Average Sale Price (ASP)\(^2\) information. In addition, we encourage CMS to require all Part B drug manufacturers to report ASP data and to increase penalties for those that don’t report price. These changes would reflect the Medicare Payment Advisory Commission’s (MedPAC) recommendations to Congress in June 2017.

Currently Part B drugs for which ASP data is unavailable (either due to the drug newly entering the market or because of lack of reporting of ASP information) are reimbursed at WAC+6%. This reimbursement rule results in excessive payments to some Part B drug manufacturers as WAC-based

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\(^1\) Wholesale Acquisition Cost (WAC) is the list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler’s supplier. Generally, it is the price established by the manufacturer before any rebates, discounts, allowances, or other price concessions are offered. The statutory definition is available in Section 1847A(c) of the Social Security Act.

\(^2\) Average Sales Price (ASP) is a manufacturer’s sales of a drug (with certain exceptions) to all purchasers in the United States in a quarter divided by the number of units of the drug sold by the manufacturer in that same quarter, net of certain price concessions and discounts. The statutory definition is available in Section 1847A(c) of the Social Security Act.
reimbursements are generally higher than that those based on ASP. According to the HHS Office of Inspector General, in 2012 at least 45 manufacturers were not required to report ASPs for 443 Part B national drug codes (NDCs) and about 74 Part B drug manufacturers that are required to submit ASP data for at least one of their Part B NDCs fail to do so.3

In addition, we take this opportunity to share our concerns on the CMS guidance (released on August 7) that gives Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs, effective January 1, 2019. We share CMS goal of lowering prescription drug costs, but we believe that any move toward step therapy should be accompanied by additional policies to protect patients and educate physicians. For example,

- When a patient changes her/his health insurance plan or physician during an active treatment of a serious medical condition, s/he should not be required to try the low-cost drug s/he had already found ineffective;
- Implementation of step therapy should be transparent, so that criteria for covering a given medication are clear to patients and physicians;
- Patients should have access to a speedy and easily understood appeals process, so they don’t face delays to recommended treatments that could compromise the efficacy of those therapies.

In addition, CMS should require unbiased physician education (such as evidence-based academic detailing programs).4 These programs have shown to be the most effective means to improve physician practices and patient outcomes. Several states, including Pennsylvania, Massachusetts, New York, Vermont, Maine, South Carolina, and the District of Columbia, have established academic detailing programs, which have proven to be cost-effective. Studies of existing state programs found that every $1 invested in these programs results in a $2 return on investment.5

Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

Community Catalyst supports the development of a bundled payment model designed to improve access, quality and efficiency of substance use disorders treatment. We appreciate the emphasis placed on increasing access to medication-assisted treatment (MAT), currently the most effective treatment available to treat opioid addiction.6 The proposed model has potential to increase MAT and it reinforces that MAT includes medication as well as counseling. Consumers receiving MAT often do not have access to the type and duration of counseling they need. A bundled payment model encourages counseling and supports the fidelity of the MAT model. Outlined below are recommendations for designing and implementing this payment model.

• **Include all substance use disorders:** We recommend that the payment model be available to treat consumers with all substance use disorders, and not be limited to opioid-used disorders. We are already seeing addiction to cocaine and methamphetamine outpace opioids in some communities,

7 and alcohol continues to take more lives than any other substance. This pattern of shifts in the most prevalent misused substance has a long history. We need to ensure our solutions help all communities tackle all addictions, including communities of color who have faced life-threatening drug issues for decades.

• **Include comprehensive services across the continuum of care:** We recommend that the bundled payment model include a range of provider types and services, such as acute care (e.g., detox, residential treatment), outpatient counseling, recovery supports, and other community supports (e.g., housing, job training, etc.). It’s particularly important that peer providers, who play an integral role in helping consumers sustain recovery, are included in this model.

• **Define episode of care:** Addiction often involves cycles of relapse and remission. We strongly urge CMS to create a payment model that is flexible and not limited to a specific timeframe or “episode.” We recommend using the ASAM Patient-Centered Opioid Addiction Treatment Payment (P-COAT) as a framework for defining the episode of care. The P-COAT model divides payments into two discrete phases. Providers would receive one payment for the first month of treatment for *Initiation of Medication-Assisted Treatment*, which includes evaluation, diagnosis, and treatment planning. Providers would then receive monthly payments for *Maintenance of Medication-Assisted Treatment* until services were no longer needed.

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• **Preserve provider choice:** Under a bundled payment model, consumers should retain their choice of provider among a variety of Medicare participating service providers that are not part of a bundled payment system, and should be able to continue receiving care from current providers regardless of their provider’s participation in the bundled payment system.

• **Incentivize providers:** We are concerned that a budget neutral model will be ineffective in improving access to care. To fully serve consumer needs, the infrastructure for substance use disorders services must be built up. We recommend that CMS increase reimbursement rates for the services of an entire care team, ranging from psychiatrists and other mental health professionals (e.g., certified addiction counselors, social workers) to nurses, and peer counselors. We also recommend providing additional reimbursement for treatment of patients with complex health care needs (e.g., co-occurring mental health or physical illness) who need more intensive service.

**Other Suggested Regulatory Changes to Address Substance Use Disorders:**

**Incentivize prevention, including SBIRT:** SBIRT is a comprehensive public health approach to addressing substance misuse and preventing addiction. SBIRT provides a unified prevention and

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intervention strategy for providers to identify alcohol or drug use through a validated screening tool and to provide brief intervention and/or linkage to treatment if the brief intervention is insufficient or a more serious problem exists.

SBIRT can help adults reduce risky use of alcohol or drugs. Research shows that SBIRT delivered to adults in primary care settings can lead to reduction in alcohol consumption, risky drinking, and emergency room visits,\(^9\)\(^{10}\)\(^{11}\) while also reducing health care costs.\(^{12}\)\(^{13}\) Studies show that SBIRT is less effective for adults with a history of long-term drug use or other complex medical problems,\(^{14}\)\(^{15}\) reinforcing that SBIRT as a misuse prevention tool and is appropriate for identifying problematic drug and alcohol use early to prevent misuse from developing into addiction.

We applaud CMS for expanding SBIRT billing to include interventions as short as five minutes. This will incentivize providers to deliver SBIRT, thereby increasing access to this important prevention strategy. However, SBIRT is currently reimbursed by Medicare only for patients who present to a physician with symptoms of illness or injury. However, the intent of SBIRT is to help providers determine if there is problematic substance misuse before a substance use disorder has developed. We recommend reimbursing providers for screening of all Medicare enrollees, instead of limiting to patients who already have problematic symptoms.

There is a precedent for using SBIRT incentive measures in Medicaid. The Oregon Health Authority established an incentive measure for Coordinated Care Organizations (CCOs) to increase the use of SBIRT services in primary care and mental health settings. To receive this incentive, CCOs were required to provide full screening and/or brief intervention services to 12% of patients 12 years of age and older. The SBIRT measure was one of 18 measures used to incentivize CCOs to improve the quality of care provided to Medicaid enrollees. The state allocated a total of $179 million in incentive payments to CCOs for their performance across all 18 measures.

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The incentive measure was in use from 2013-2016 and led to significant increases in SBIRT billing in primary care clinics across the state, from 6% of consumers receiving screening and/or brief intervention services in 2014 to 20% in 2016. In 2016, each of the participating CCOs achieved their target for this measure. The original measure, which used claims data, was removed in December 2016 and will be reinstated in 2019 when it is revised to align with electronic health record data reporting.

**Add Recovery Supports:** We recommend including recovery support services as part of outpatient rehabilitation under Medicare Part B. Peer support services\(^{16}\) and other recovery support services\(^{17}\), which help consumers get healthy and maintain recovery, are not included under Medicare. The Centers for Medicare and Medicaid Services recognize the important role of peers\(^{18}\) and encourage states to include recovery support services in state Medicaid plans. Making these cost-effective services available to Medicare beneficiaries would be an important step in addressing substance use disorders for seniors and people with disabilities.

**CY 2019 Updates to the Quality Payment Program**

We are pleased to see CMS working to continue to move the health care system from one that is based solely on fee-for-service, towards a system that focuses on better coordination, quality and value of care. We offer the following comments on the proposed update to the QPP:

- **Low Volume Threshold:** While we recognize the unique barriers small and rural practices face to successfully participating in the quality payment program, we are concerned that continuing to expand exemptions will diminish the overall effectiveness of the QPP and prevent patients in rural areas from seeing the benefits of a value based health-system. We support CMS’ decision to allow some practices that meet the low-volume threshold to opt into the QPP program and ask that, rather than continuing to exclude small and rural practices, CMS consider additional supports and modifications that might make it easier for these practices to participate.

- **Quality measures:** Appropriate quality measures are critical for ensuring that the QPP is working to improve health outcomes and patient experience. This means measuring what is actually important to patients, valuing outcomes over process, and including patient reported measurements. We applaud the administration’s decision to add more patient reported quality measures to the available MIPS quality measures and to accelerate the phasing out of topped-out measures. We also support CMS’s commitment to replace more process measures with outcome measures. As CMS continues to refine its quality measurement strategy we ask that it prioritize measures of equity and health disparities and stratify quality data by race, ethnicity, sex, gender identity, sexual orientation, primary language, and disability status.

- **Accounting for Risk Factors in the Final Score:** We support the continued use of the complex patient bonus and encourage CMS to continue its consideration of how best to account for social


\(^{17}\) Substance Abuse and Mental health Services Administration “Recovery and Recovery Support,” 2017. Available at: https://www.samhsa.gov/recovery

\(^{18}\) Centers for Medicare and Medicaid Services, State Medicaid Directors Letter, August 15, 2007. Available at: https://facesandvoicesofrecovery.org/file_download:inline/0d557479-73f6-48ac-abc0-600dd3ddbb09
risk factors in the QPP. In particular, we encourage CMS to implement recommendations from the Department’s Assistant Secretary for Planning and Evaluation, the National Academy of Sciences, Engineering, and Medicine, and the National Quality Forum on how to best adjust value-based payments to account for social risk factors. It is vitally important to ensure that providers whose patients disproportionately have more complex health and social needs are not unfairly disadvantaged. Otherwise, initiatives designed to improve the quality of care and health outcomes may result in worsening outcomes for these more complex patients and increased health disparities, as the providers who care for them face additional financial constraints as a result of financial penalties. At the same time, the quality of care and health outcomes for patients with more complex health and social needs must also improve.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

We appreciate CMS’s effort to improve price transparency as prices vary depending on where the service is provided, what kind of insurance the patient has, whether the provider offers robust financial assistance, and other factors. Though transparency is crucial in helping patients make the health care decisions that are right for them, price transparency alone does not improve patients’ health outcomes and experiences or reduce health care costs. In fact, only 7 percent of consumers’ out of pocket health care spending is estimated to be on “shoppable” services, suggesting that the purchasing power of consumers has limited ability to drive affordability and quality of care.

Transparency efforts are often irrelevant for patients who have little choice in their providers, such as patients with complex medical needs, people in plans with closed networks, and people who live in rural areas or areas with provider monopolies. For instance, people with rare or complex health needs are likely to face limited choices of providers or treatment options for their condition. These populations also benefit most from care that is well coordinated and grounded in longitudinal relationships with care providers, so changing providers or treatment options to get the best price might actually be harmful for their health outcomes. For people with physical disabilities, the accessibility of the provider’s location (for example, is it wheelchair accessible) will likely matter more than the price of a service. The same is true of people with limited English proficiency, who will need to prioritize providers that offer reliable translation services and culturally competent care. Patients in rural or underserved areas may also find price transparency efforts irrelevant if they are not also paired with efforts to improve access to care in these areas. As you continue your work, we ask that you take into account the differing impacts these policies may have on vulnerable and complex patient populations.

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19 Tax-exempt hospitals, for example, are required to have and widely community their financial assistance policies to patients and the public and to clarify which providers and services are covered. See Community Catalyst, “What Does the Affordable Care Act Say about Hospital Bills?” (June 2015). Available at https://www.communitycatalyst.org/resources/publications/document/CC-ACHospitalBillsReport-F.pdf?1434480883.


To support your transparency efforts, we recommend CMS follow the below principles:

- **Take into account the unique needs of different patient populations, including patients with complex health needs;**
- **Empower consumers by improving their ability to access the highest quality care and select providers that fit their needs while protecting them from the financial burden of increased out-of-pocket costs;**
- **Connect consumers directly with information about financial assistance and billing options; and**
- **Link information about price to meaningful and understandable quality data.**

We strongly encourage CMS to consider the following patient-friendly transparency ideas that could actually improve patients’ health outcomes and make health care more affordable:

**Transparency in provider network and service charges.** In Medicare, patients are held harmless from out-of-network charges in emergency situations. For covered non-emergency services provided by out-of-network providers, they are not held liable for more than their cost-sharing requirements. In these cases, Medicare Advantage plans reimburse the balance billed amount directly to non-participating providers. In addition, Medicare providers are also prohibited from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments from beneficiaries enrolled in the Qualified Medicare Beneficiaries program.

Unfortunately, these protections are not extended to insured patients enrolled in private health insurance markets. Evidence shows privately insured patients are often exposed to high out-of-network charges.23 Many people only find out through a medical bill that they received a service from an out-of-network physician--for instance, an anesthesiologist in the emergency room assisting during a surgery, or a pathologist examining a biopsy.24 These bills can add up to hundreds or thousands of dollars, leaving consumers with little recourse and potentially devastating medical debt.25 To protect privately insured patients from high out-of-network charges and improve this financial stability, we urge CMS to:

- **Require accurate provider directories.** The first step is to require hospitals and health plans to keep their provider directories are up-to-date, readable, easy to access and include necessary information that enable enrollees to find providers that meet their needs.
- **Work with Congress to put in place policies that hold patients harmless for out-of-network charges in emergency situations.** For non-emergency care, patients should only be responsible for in-network cost-sharing (i.e. deductibles, copays or coinsurance) specified in their health insurance policy if they accidentally receive care from out-of-network providers because of inaccurate provider directories, unavailable in-network providers for covered services, or unexpectedly receiving care from out-of-network providers in an in-network facility.


● **Require accurate price information.** Though many patients might not be in the position to select providers, this requirement would help those who opt to receive care from out-of-network providers to anticipate their out-of-pocket costs and compare prices. CMS should require both health plans and providers to notify patients of provider network status and warn them about potential out-of-network charges in writing. Patients should only be responsible for out-of-network charges if they receive and sign in advance a financial consent that includes estimated price information. An estimate of out-of-network charge should contain the following information: (1) the total price for care; (2) any negotiated or discounted prices set by patient’s insurer; (3) patient share of the bill; and (3) guaranteed, binding estimates.26

**Transparency in patient-centered quality measures.** Even in situations where consumers are able to “shop” for care, the goal of consumer choice is meaningless without clear and meaningful information on quality. The drive towards higher value care in the U.S. involves not only lowering costs, but also improving outcomes by ensuring health care dollars are spent effectively on high-quality services. Alongside price information, patients should have access to meaningful and easy-to-understand information about the quality of the provider they are considering. This should include patient experience and patient reported outcome measures (PROMs) that reflect outcomes meaningful to patients. A strong, patient-centered quality strategy will be critical for transparency initiatives.

**Transparency in provider billing and collections.** The ACA made important strides towards this goal by establishing requirements around fair, transparent billing for non-profit hospitals,27 but these protections do not extend to other provider types.28 CMS should continue to work with the Internal Revenue Service, and other federal agencies to improve patient protections and increase fairness and transparency with regard to provider billing and collections by:

- Broadly sharing information about hospital financial assistance policies (FAPs) on a publicly available, free searchable website such as healthcare.gov.
- Exploring options for expanding provider financial assistance and consumer protections against overcharging and problematic collections tactics to a broader range of providers, perhaps through accountable care organization (ACOs) requirements.
- Gathering data and studying the impact of provider billing and collection policies on medical debt. The Consumer Financial Protection Bureau has been doing groundbreaking research on the prevalence of medical debt and its sources and that research should continue. This work has helped to inform and deepen understanding of how medical debt varies by geography, race, gender, insurance status, and income.29

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- Expanding financial assistance and billing protections to all hospitals (regardless of ownership status) receiving Disproportionate Share Hospital (DSH) funds.

We appreciate the opportunity to comment on changes to the Medicare Physician Fee Schedule for CY 2019. Please do not hesitate to contact me at ahwang@communitycatalyst.org should you have any questions or if you would like additional information.

Sincerely,

Ann Hwang, MD
Director, Center for Consumer Engagement in Health Innovation