



September 24, 2018

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445–G, Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Proposed Policy Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Levering Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model [CMS-1695-P]**

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs and other policy changes for CY 2019. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

**Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in Utilization of Outpatient Services**

**CMS Proposals:** The Centers for Medicare & Medicaid Services (CMS) is proposing to expand site neutral payments for all outpatient clinic visits in its Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System proposed rule. If finalized and implemented, this rule would reduce the payment differences between sites of service, including hospital outpatient departments (HOPDs) and freestanding community clinics.

**ACP Comments:**

Key to the creation of Section 603 of the Bipartisan Budget Act (BBA) is stemming consolidation in the health care marketplace. Policymakers are recognizing the negative effects of vertical integration on the independent physician practices, health care costs, and access to care. Section 603 of the BBA was intended to curtail consolidation, preserve patient choice in care settings, and decrease costs in the Medicare system.

**ACP strongly supports this proposal and appreciates that CMS is proposing to exercise authority to control unnecessary increases in the volume of covered hospital outpatient department services by applying a Physician Fee Schedule (PFS)-equivalent payment rate for the clinic visit service when provided at an off-campus provider-based department (PBD) that is paid under the OPFS.**

ACP believes that site neutrality is good policy for Medicare, Medicare beneficiaries, and the health care system as a whole. Historically, Medicare has typically paid a higher rate for the same service when performed at a HOPD rather than a physician's office. Site of service payment differentials create an incentive for hospitals to acquire physicians' practices and rebrand them as HOPDs, causing the magnitude of this problem to grow over time. While site-of-service payment differentials are not the only factor driving hospitals to acquire physician practices, they likely do play a major role. Embracing a policy of site-neutral payments could thus save Medicare considerable dollars. **ACP supports CMS for its proposal to expand site-neutral payment in Medicare because we do not believe that care delivered in a HOPD should be paid a higher rate when that care is not dependent on the hospital facility and its associated technologies. Rather, in line with the College's High-Value Care initiative,<sup>1</sup> the College supports delivery of care in the most efficient setting, while maintaining quality of care.**

Additionally, any changes must not negatively impact Safety-Net organizations, deny or restrict coverage of care provided by qualified and approved clinicians, or jeopardize access to primary and preventive care for millions of Americans who rely on our Nation's already stretched health care safety net. Coverage decisions should be based solely on medical evidence, best practices, and qualifications. Provider-based billing should not be used as a mechanism for hospitals to recoup/stabilize funding or as a means of ensuring access to care. Ensuring adequate hospital funding and patients' access to care can better be addressed and supported through other means, such as increased/improved health insurance coverage, strengthened workforce policies, and delivery system reforms.

**New Clinical Families of Services at Off-Campus PBDs Excepted from Section 603 of the Bipartisan Budget Act of 2015**

**CMS Proposals:** In CY 2017 OPFS rulemaking, CMS proposed, but did not finalize, a policy that off-campus PBDs excepted from Section 603 of the Bipartisan Budget Act of 2015 could

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<sup>1</sup> <https://www.acponline.org/clinical-information/high-value-care>

continue to be paid at OPPS rates for items and services in each of the 19 proposed “clinical families of services” if that PBD furnished and billed for a service in that clinical family of services prior to November 2, 2015. While CMS did not finalize this policy in CY 2017, CMS noted that it would continue to monitor the volume of services at excepted PBDs to determine if future rulemaking should address service-line expansion. In the CY 2019 OPPS/ASC proposed rule, CMS is proposing to pay for services in new clinical families of services furnished at excepted off-campus PBDs under the PFS instead of the OPPS.

**ACP Comments:**

CMS correctly surmises from Section 603 of the BBA that allowing “excepted” facilities to expand beyond their current scope of services will perpetuate the acquisition of community-based practices by hospitals and fail to achieve the BBA’s intent of curtailing consolidation and achieving savings in the Medicare system. Payment differentials in Medicare have put community clinics at a direct disadvantage in the delivery of the same care provided in HOPDs, resulting in a significant shift of outpatient care from the community setting to the HOPD. As noted above, the College does not support provider-based billing for care delivered in an outpatient, hospital-system owned practice when that care is not dependent on the hospital facility and its associated technologies. ACP supports care delivery in the most efficient setting, with quality of care being maintained. **Therefore, ACP supports CMS’ proposal to pay for new clinical families of services at excepted off-campus PBDs at the PFS-equivalent rate.**

**Proposed Updates to the Hospital Consumer Assessment of Healthcare Providers and Systems Survey**

**CMS Proposals:** In the 2018 IPPS final rule, CMS finalized a change in the Hospital Inpatient Quality Reporting (IQR) Program that removed the previously adopted pain management questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and replaced them with new Communications about Pain questions. The revised questions are focused on communication with patients about pain and treatment of pain rather than the former questions that assessed how well their pain is controlled. The updated questions are effective for discharges beginning in January 2018, for payment determinations in FY 2020 and subsequent years, and they will be publicly reported on the Hospital Compare website beginning October of 2020.

CMS continues to receive feedback from stakeholders expressing concerns about the revised HCAHPS questions related to communication with patients about pain and their potential to pressure hospital staff to prescribe more opioids to achieve higher HCAHPS scores. Additionally, the President’s Commission on Combatting Addiction and the Opioid Crisis recommended the removal of the HCAHPS pain management questions. Therefore, out of an abundance of caution, CMS proposes to remove the Communication about Pain questions from the HCAHPS survey beginning with discharges in January 2022, for payment determinations in FY 2024 and subsequent years.

**ACP Comments:**

**In light of the ongoing concerns with the potential for incentivizing opioid prescribing, the College strongly supports the proposal to remove the Communication about Pain measures from the HCAHPS Survey in the Hospital IQR Program.** ACP supports moving toward patient- and family-centeredness measures that do not create unintended adverse consequences. However, given continued concerns about the potential for the current HCAHPS pain measures to create financial incentives that could inadvertently incentivize inappropriate opioid administration and prescribing, the College supports removing the current measures from the HCAHPS survey. We further encourage CMS to make this change as soon as is feasible, effective with discharges in January 2020 if possible. In the interim, while the Communication about Pain measures are still part of the HCAHPS survey, we recommend that CMS remove these measures from the scoring calculation to minimize any potential adverse consequences as a result of incentivizing opioid prescribing.

Patients experience varied types of pain, with various goals of management, depending on features of the clinical situation, such as: underlying diagnosis, acute vs. chronic nature of the pain, life expectancy, prior narcotic use, dependence, and/or abuse history, and other factors which must be taken into account by the prescribing clinician. HCAHPS surveys should not include pain management measures that may have the effect of causing inappropriate prescribing of opioids. We also recommend that CMS provide hospitals with appropriate guidance related to how the information gathered through the CAHPS survey is intended for use by hospitals. For example, if the data is not meant to be stripped down to compare wards, floors, hospital staff, etc. within a hospital, CMS should more explicitly state that to avoid instances where the data is inappropriately used to compare, assess, and incentivize clinicians and other hospital staff.

**Proposed CY 2019 Packaging Policy for Non-opioid Pain Management Treatments**

**CMS Proposals:** CMS is seeking comments on non-opioid alternatives in the outpatient setting including peer-reviewed evidence that demonstrates whether and how non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure. The Agency is also seeking ideas on policy changes that are needed to help prevent opioid use disorders and improve access to treatment in Medicare. This includes identifying barriers that inhibit access to non-opioid pain treatment and management alternatives as well as payment methodologies and coverage.

**ACP Comments:**

The College appreciates the opportunity to provide CMS with feedback on policy changes that prevent opioid use disorders and improve access to treatments including non-opioid and non-pharmacologic pain management alternatives. Over the last several years, ACP has published a series of policy papers on this topic that provide our prescription for policy reforms to curb the abuse of prescription drugs including: [The Integration of Care for Mental Health, Substance Abuse, and other Behavioral Health Conditions into Primary Care](#), [Prescription Drug Abuse](#), and [Health and Public Policy to Facilitate Effective Prevention and Treatment of Substance Use Disorders Involving Illicit and Prescription Drugs](#). These policy papers provide a resource for you

as you examine policies on this topic. We believe that CMS can improve the treatment of our patients with opioid use disorders and substance use disorders (OUDs, SUDs) by reforming Medicare and Medicaid to incentivize the integration of behavioral health into primary care. Our policies also support the treatment of patients with opioid use disorders with non-pharmaceutical therapies when clinically appropriate, additional education for physicians concerning the risk and benefits of treatment of pain with opioids, and reduction of administrative burdens associated with the use of prescription drug monitoring programs (PDMPs), as outlined below and further detailed in recent letters to the U.S. Senate.<sup>2,3</sup>

### *Eliminate Barriers to Non-opioid and Non-pharmacologic Pain Management Alternatives*

ACP supports removing barriers to evidence-based non-opioid and non-pharmacologic pain management services that do not involve potentially addictive medications. ACP believes that to facilitate improved access to non-opioid methods of pain control, CMS should reduce cost sharing and eliminate the need for prior authorization for non-opioid pain management strategies. The CDC Guideline for Prescribing Opioids for Chronic Pain states, “Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.” The guideline lists several interventions, such as cognitive behavioral therapy, physical therapy, and weight loss for knee osteoarthritis, which may alleviate chronic pain. A clinical practice guideline issued by ACP recommends noninvasive treatments for acute, sub-acute, and chronic low back pain.<sup>4</sup>

However, Medicare and Medicaid often limit coverage of non-pharmacologic or non-opioid pain management services. For example, Congress only recently approved legislation to permanently remove Medicare caps on physical therapy and does not cover massage therapy, acupuncture, or other services mentioned in the CDC guideline on chronic pain and other clinical guidelines. A growing number of state Medicaid programs<sup>5</sup> are electing to cover non-opioid pain management services but few encourage their use. Some insurance plans establish step therapy (or “fail-first”) policies that require alternative treatment approaches be proven ineffective before another intervention is covered, and CMS recently announced that Medicare Advantage plans will have the option of utilizing step therapy for Part B drugs.<sup>6</sup> ACP and other physician organizations opposed this policy change due to its potential to create barriers to

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[https://www.acponline.org/acp\\_policy/letters/response\\_to\\_senate\\_finance\\_committee\\_on\\_opioid\\_substance\\_use\\_disorder\\_treatment\\_policy\\_recommendations\\_2018.pdf](https://www.acponline.org/acp_policy/letters/response_to_senate_finance_committee_on_opioid_substance_use_disorder_treatment_policy_recommendations_2018.pdf)

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[https://www.acponline.org/acp\\_policy/letters/acp\\_letter\\_to\\_help\\_finance\\_leaders\\_on\\_opioid\\_crisis\\_response\\_act\\_2018.pdf](https://www.acponline.org/acp_policy/letters/acp_letter_to_help_finance_leaders_on_opioid_crisis_response_act_2018.pdf)

<sup>4</sup> <http://annals.org/aim/fullarticle/2603228/noninvasive-treatments-acute-subacute-chronic-low-back-pain-clinical-practice>

<sup>5</sup> <https://nashp.org/wp-content/uploads/2016/09/Pain-Brief.pdf>

<sup>6</sup> <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>

appropriate and timely treatment of patients.<sup>7</sup> The evidence base to support non-pharmacologic and non-opioid pain management interventions should be expanded, and as the effectiveness of interventions is determined, Medicare and Medicaid must cover them so that the lowest-risk, most effective approach is accessible to the patient.

Reduced cost-sharing and removing burdensome prior authorization or step therapy protocols for these non-opioid alternatives will help promote better patient access. In addition to limiting the use of prior authorization, CMS should develop a standardized electronic format for prior authorization requests related to Part D to reduce administrative burden and enable beneficiaries to more promptly receive needed drugs and therapies. ACP provided detailed recommendations<sup>8</sup> on improving prior authorization within Medicare Part D but also pressed upon the need for greater harmonization of standards implementation and automation of prior authorization across the health care industry, as a goal for the future. Prior authorization and other administrative burdens consume a massive amount of physician and staff time and contribute to physician burnout, delays in appropriate patient care, and medical errors. To facilitate the elimination, reduction, alignment, and streamlining of administrative tasks, all key stakeholders should collaborate in better utilizing existing health information technologies, as well as developing more innovative approaches.

### *Integration of Behavioral Health in Primary Care*

The College strongly supports reforming Medicare and Medicaid payment policies designed to better integrate behavioral health, including screening, referral and treatment of opioid and substance use disorders, into the primary care setting. Primary care is the appropriate platform to care for these patients as it is often the first point of contact of care for patients with these disorders. Many patients with chronic pain present co-morbid behavioral health conditions, including anxiety and depression, which can have an effect on pain management.<sup>9</sup>

Unfortunately, many barriers to the seamless integration of behavioral and primary care exist in the physician payment structures of Medicare and Medicaid. Behavioral and physical health care providers have a long history of operating in different care silos and reimbursement policies have not always incentivized integrated, team-based care. Recently, Medicare has developed new payment codes for certain integration models, such as the Psychiatric Collaborative Care Model (CoCM).<sup>10</sup> We encourage CMS to consider expanding models such as the patient-centered medical home, currently being tested in the Innovation Center as the Comprehensive Primary Care Plus (CPC+), to provide a foundation for the integration of behavioral and primary care to manage pain and treat patients with OUD or SUDs. Its bundled monthly pay components also provide a means to financially support the required infrastructure and clinical resources necessary for effective integration. Team-based care is

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<sup>7</sup> [https://www.acponline.org/acp\\_policy/letters/letter\\_to\\_cms\\_on\\_step\\_therapy\\_part\\_b\\_drugs\\_2018.pdf](https://www.acponline.org/acp_policy/letters/letter_to_cms_on_step_therapy_part_b_drugs_2018.pdf)

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[https://www.acponline.org/acp\\_policy/letters/letter\\_to\\_rep\\_schweikert\\_on\\_standardizing\\_electronic\\_prior\\_authorization\\_for\\_safe\\_prescribing\\_act\\_2018.pdf](https://www.acponline.org/acp_policy/letters/letter_to_rep_schweikert_on_standardizing_electronic_prior_authorization_for_safe_prescribing_act_2018.pdf)

<sup>9</sup> [https://www.integration.samhsa.gov/about-us/Pain\\_Management\\_Webinar\\_Slides.pdf](https://www.integration.samhsa.gov/about-us/Pain_Management_Webinar_Slides.pdf)

<sup>10</sup> <https://catalyst.nejm.org/medicare-payment-behavioral-health-integration/>

especially necessary when caring for patients who have or are recovering from substance use disorders.<sup>11</sup> CMS should continue to test team-based, coordinated care models that are designed to treat the whole patient, including the patient's pain management needs, in a manner that emphasizes use of evidence-based non-opioid pharmacologic and non-pharmacologic pain management interventions.

### *Increasing Access to Medication Assisted Treatment and Recovery Programs*

ACP strongly supports lifting barriers to ensure that our patients receive access to medications to treat opioid use disorders and to reverse overdoses. Medicare and Medicaid benefits should be strengthened to improve access to evidence-based medication-assisted treatment (MAT). According to the Kaiser Family Foundation, 14 state Medicaid programs do not cover the full array of MAT, buprenorphine (including the buprenorphine/naloxone formulation), naltrexone, or methadone.<sup>12</sup>

We recommend that CMS consider conducting a demonstration, such as the one included in President Trump's 2019 Budget Proposal, to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Under this program, Medicare would cover methadone treatment or similar medication-assisted therapy for beneficiaries with OUDs. A corresponding expansion of medication-assisted treatment is also proposed for Medicaid beneficiaries, who struggle with addiction to opioids and other substance use disorders. If these programs are successful in key metrics, such as reducing deaths, hospitalizations, and emergency room visits for beneficiaries who receive these treatments, the demonstration could be expanded nationwide.

We encourage CMS work with the Substance Abuse and Mental Health Services Administration (SAMHSA) to consider lifting the cap on the number of patients who can receive buprenorphine, if a physician has been trained in proper prescribing practices. Medicare and Medicaid should cover and remove onerous limits on medications for overdose prevention and MAT, including burdensome prior authorization rules or lifetime limits on buprenorphine that prevent medically necessary care. Oversight and enforcement efforts should be strengthened to protect against misuse, diversion, and illegal sale of buprenorphine and other opioid treatment drugs. Physicians are reluctant to apply for waivers for MAT due to the complexity of this patient population, the lack of mental health and psychosocial support, and time constraints in their practice. More attention should be directed to preparing and supporting buprenorphine-waivered physicians to improve confidence and facilitate team-based care as well as reducing the growing administrative and paperwork burden on physicians and staff to allow more time to care for patients.

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<sup>11</sup> <https://www.ncbi.nlm.nih.gov/books/NBK92054/>

<sup>12</sup> <https://www.kff.org/medicaid/state-indicator/states-reporting-medicare-coverage-of-medication-assisted-treatment-mat-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

ACP recommends that Medicare and Medicaid facilitate use of physician support initiatives, such as mentor programs, shadowing experienced clinicians, and telemedicine, that can help improve education and support efforts around substance use treatment. Professional support resources, such as Providers' Clinical Support System and hub-and-spoke programs like Project Extension for Community Healthcare Outcome for Opioid Therapies, can link primary care physicians to health care professionals experienced in substance use disorder treatment and can improve physician confidence in buprenorphine prescribing practices and other areas of substance use disorder treatment.

### *Prescription Drug Monitoring Programs*

ACP supports the establishment of a national PDMP that would analyze and collect data related to the prescribing of controlled substances. Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting program. ACP strongly recommends that prescribers and dispensers check PDMPs in their own and neighboring states (as permitted) prior to writing and filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.

Several policies must be pursued to reduce administrative burdens associated with PDMPs, including ensuring interoperability with electronic health record systems. According to a recent report from the Pew Charitable Trust,<sup>13</sup> the integration of PDMP data into a patient's health IT record would save the physician time and reduce administrative hassle associated with this task. The report notes that "integration with health IT makes PDMP data available to prescribers as part of their workflow without the need for multiple user accounts, log-ons, or user interfaces, thus saving prescribers time and effort. One study, involving focus groups of 35 prescribers from nine states, identified time spent accessing a report as a barrier to PDMP use and recommended integration with health IT as part of the solution."

### **Price Transparency**

**CMS Proposals:** CMS expresses concern about continuing patient challenges due to insufficient price transparency, including surprise out-of-network bills for out-of-network physicians who provide services at in-network facilities, unexpected facility fees, and other charges. To promote greater price transparency for patients, the agency is considering ways to improve the accessibility and usability of charge information and to engage suppliers and clinicians in consumer-friendly communication of price to help patients better understand their potential financial liability and compare charges for similar services across clinicians and settings.

### **ACP Comments:**

The College supports transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. ACP

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<sup>13</sup> [http://www.pewtrusts.org/~media/assets/2016/12/prescription\\_drug\\_monitoring\\_programs.pdf](http://www.pewtrusts.org/~media/assets/2016/12/prescription_drug_monitoring_programs.pdf)



also agrees action should be taken to increase protection for patients who find themselves subject to unexplained or surprise bills through no fault of their own, particularly those incurred during emergency or other medical situations in which additional services are provided by out-of-network clinicians without the patient's prior knowledge.

However, the complexity of medical billing can make it difficult or misleading to come up with a standard or average price for a particular service. Prices can vary widely based on information unique to the individual patient and visit, including comorbidities, necessary follow-up care or tests, and site of service, among a range of other factors. Pricing for self-pay patients and those privately insured are determined through two distinct processes that would require separate approaches to price transparency. Beyond that, individual hospital-payer contracts can bundle services, treatments, and drugs completely differently, making direct, national, or even regional price comparisons difficult. What matters most to the patient is not the total cost of a service; it is their own out-of-pocket responsibility.

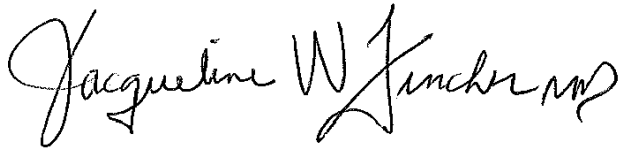
Health plans are in the best position to communicate important coverage information that impacts their customers' total out of pocket cost. The College urges CMS to encourage health plans to share information with clinicians and patients regarding important coverage, cost, and quality information, such as whether a clinician is in-network or out-of-network. Integrating cost, quality, and coverage data into electronic health records systems, quality clinical data repositories, regional health information exchanges, or all payer claims databases would help physicians to be more effective partners in helping patients to navigate this information and make informed, cost-effective decisions about their care. The growing prevalence of narrow network plans exacerbates this problem and should be separately studied and addressed. ACP supports state-level efforts to prohibit "gag clauses" and similar contractual arrangements that interfere with the transparency of relevant health data. The College also supports the development of APMs, which we feel also show promise in aligning financial incentives to facilitate enhanced communication and coordination between multiple providers and cost-effective referral patterns to high-value, in-network providers.

**Price should never be used as the sole criterion for selecting a physician or service; it should always be accompanied by quality information critical to understanding the total value of care, such as metrics about patient safety and health outcomes. If not, patients may simply defer to the lowest-cost providers, which could put them in a vulnerable position.** At the same time, quality data released should be thoroughly vetted before being released to the public so as not to adversely penalize providers who care for vulnerable patient populations that are predisposed to worse outcomes, so as not to exacerbate existing social determinants of health. All information should be communicated in a readily accessible way to patients at all levels of health literacy and presented in a way that clearly articulates which services, treatments, and prescription drugs are included (and not included) in a given price, so that patients can make meaningful comparisons across settings of care and providers. Patients should also be made aware of the possibility of added costs due to common complications or add-on treatments. Releasing pricing information that is taken out of context, flawed, or incomplete has the potential to be more harmful to patients than lack of information.

**As CMS looks to possibly regulate in this complex and sensitive pricing environment with the potential for wide-reaching implications on payers, providers and patients alike, the College recommends a graduated, targeted approach to any new price transparency initiatives and frequent consultation with stakeholders throughout the process. Gradual implementation will help to minimize the potential for major disruptions to physician payments and therefore patient care.**

ACP appreciates the opportunity to comment on the CMS 2019 OPPI and ASC Proposed Rule. Thank you for your time and consideration. Please contact Brian Outland, PhD, by phone at 202-261-4544 or e-mail at [boutland@acponline.org](mailto:boutland@acponline.org) if you have questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline W. Fincher, MD, MACP  
Chair, Medical Practice and Quality Committee  
American College of Physicians