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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Sabotage: The Trump Administration's Attack on Health Care"

October 23, 2019

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

The Honorable Frank Pallone, Jr. (D-NJ)

1. **The Program of All-Inclusive Care for the Elderly (PACE) program allows older Americans eligible for nursing home care to remain in the community. In 2015, Congress passed the PACE Innovation Act of 2015 (PIA), which allows the Centers for Medicare & Medicaid Services (CMS) to waive Medicare and Medicaid program requirements so that the Center for Medicare & Medicaid Innovation (CMMI) can test PACE pilot programs in populations not previously served. CMMI issued two Requests for Information on PACE pilots in 2016 and 2017 but since then has not taken further action. Why are PACE-specific pilots no longer a priority for CMMI?**

CMS Response: The Programs of All-Inclusive Care for the Elderly (PACE) provide comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. PACE is a program under Medicare, and states can elect to cover PACE as an optional Medicaid benefit. An interdisciplinary team of health professionals provides PACE participants with coordinated care. For most participants, the comprehensive service package enables them to remain in the community rather than receive care in a nursing home. Financing for the program is capitated, which allows providers to deliver all services participants need rather than only those reimbursable under Medicare and Medicaid fee-for-service plans.

PACE enrollment has increased by over 25 percent in the last three years, and we have taken important steps to strengthen the program. In June 2019, CMS published a final rule to update and modernize the PACE program, the first major update to the program since 2006. To expand access to PACE, our final rule provides more administrative flexibility and regulatory relief for PACE organizations. The final rule also includes provisions to strengthen protections and improve care for PACE participants.

The PACE Innovation Act of 2015 (P.L. 114-85) provides the Innovation Center with the authority to waive certain requirements of section 1934 of the Social Security Act in order to test PACE-like models, for instance, to include additional populations, such as populations under the age of 55 or those who do not qualify for a nursing home level of care. In 2016, and again in

2017, CMS issued a request for information seeking comments on potential models and populations who would benefit from PACE-like models.

In November 2019, CMS announced a new PACE-like track within the Innovation Center's Direct Contracting Model. Direct Contracting is a set of voluntary payment model options that create opportunities for organizations to participate with CMS in testing risk-sharing arrangements aimed at reducing expenditures and preserving or enhancing quality of care for Medicare fee-for-service beneficiaries. Under the Direct Contracting Model, there will be three types of participating organizations with different characteristics and operational parameters, including organizations that serve Medicare fee-for-service beneficiaries with complex needs, such as dually eligible beneficiaries. These "High Needs Population" organizations are expected to use a model of care designed to serve individuals with complex needs, such as the one employed by PACE, to coordinate care for their aligned beneficiaries. We are encouraged by the fact that numerous PACE organizations have expressed interest in the new model.

CMS will continue to consider future opportunities to conduct model tests through the Innovation Center using the waiver authority provided by the PACE Innovation Act. We are also focused on developing other kinds of models in which a range of providers would provide Medicare services on a capitated or at-risk total-cost-of-care basis. We are working to ensure these models provide opportunities to test innovative ways to serve people of all ages who have complex chronic conditions or functional impairments, building on what has worked well with the PACE clinical approach.

2. **According to an October 15, 2019, Kaiser Family Foundation issue brief, nearly half (47%) of community health centers report that their immigrant clients are declining to enroll in Medicaid, and approximately a third (32%) report their patients have dropped Medicaid coverage or decided not to renew Medicaid coverage. Interviews with health center staff indicate that fear and confusion surrounding recent immigration policies contributed to these drops in enrollment. This reported decrease in immigrant patients enrolling in Medicaid seems to confirm concerns raised in a statement on August 13, 2019 by American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Osteopathic Association, American College of Physicians, and American Psychiatric Association that new immigration policies such as the public charge rule, will lead to more uninsured patients.**

   What outreach and education activities has CMS undertaken to specifically correct any potential misinformation about the public charge rule among Medicaid beneficiaries?

CMS Response: CMS supports Medicaid/CHIP enrollment by pursuing several strategies in an effort to inform the public about opportunities for eligible children and teens to enroll. This includes efforts of the Connecting Kids to Coverage National Campaign, which utilizes multi-cultural outreach and engages with families who have children or teenagers who are eligible for

Medicaid and CHIP to raise awareness about available coverage under the program. The Campaign also provides outreach guides and toolkits that can be used to help states, community organizations, schools, health care providers, and others organize and conduct successful outreach activities. In July 2019, CMS announced the availability of $48 million in outreach and enrollment grants. The grant awards, which will have a 3-year performance period, will continue to support activities aimed at informing families of the availability of free or low-cost health coverage under Medicaid and CHIP, identifying children likely to be eligible, and assisting families with the application and renewal process. In January 2020, CMS awarded an additional $6 million in available funds over three years to increase the enrollment and retention of American Indian/Alaskan Native children who are eligible for but not enrolled in Medicaid or CHIP.

Furthermore, to help and support general enrollment efforts, CMS offers a set of Medicaid Fact Sheets aimed at helping consumers understand the basics of eligibility, program benefits, and enrollment processes.[1] To ensure these are as useful as possible, we also offer to customize the materials with local phone numbers, logos and other information deemed necessary. Medicaid.gov includes information and guidance on optional coverage for lawfully residing immigrant children and pregnant women. Information on states providing Medicaid or CHIP coverage to lawfully residing immigrant children and pregnant women may be found here: https://www.medicaid.gov/medicaid/enrollment-strategies/medicaid-and-chip-coverage-lawfully-residing-children-pregnant-women. HealthCare.gov also includes information on "public charge" status and USICS regulations, including information on Medicaid and CHIP. It is important to note that, for children under age 21 and pregnant women, enrollment in Medicaid or the Children's Health Insurance Program (CHIP) is not considered a public benefit under the public charge rule. CHIP is not covered by the "public charge" rule, while Medicaid enrollment is not considered as a public benefit for non-citizens under the age of 21. This information is available here: https://www.healthcare.gov/immigrants/lawfully-present-immigrants/

3. **With Open Enrollment now underway, there is widespread confusion and fear in the immigrant community regarding the public charge rule, despite it currently being enjoined from being implemented. While the public charge rule only factors Medicaid usage and not the Affordable Care Act (ACA) subsidies, individuals may not be aware that they would not be penalized by use of ACA subsidies. In fact, an Urban Institute survey found that one in seven adults in immigrant families reported they avoided all public benefits out of fear of risking their future green card status. What actions is CMS taking to ensure that families considering enrolling in health insurance do not avoid doing so because of confusion related to public charge fears?**

CMS Response: HealthCare.gov includes information on "public charge" status and USCIS regulations. This includes content stating that enrollment in a Marketplace plan with or without a

[1] Available at https://www.medicaid.gov/medicaid/outreach-tools/supporting-enrollment-efforts/index.html

premium tax credit is not a public benefit under the public charge final rule. The website advises consumers to contact USCIS directly before continuing their Marketplace application if they think the USCIS regulations might affect them.[2]

The Honorable Diana L. DeGette (D-CO)

1. **The President's Executive Order 13890 has language that makes it easier for innovative healthcare products to gain Medicare coverage, so patients can have better access to new, exciting innovation.**

    a. **How long, post-Food and Drug Administration (FDA) approval, does it typically take to open a national coverage decision?**
    b. **How long does it take for the agency to make a final judgment on Medicare coverage?**
    c. **What other tools could you use from Congress in order to help get innovative healthcare products to patients faster, particularly since they have already been approved as safe and efficacious by FDA?**

CMS Response: CMS uses multiple pathways to provide Medicare coverage of innovative technologies to beneficiaries, and we strive to provide fast coverage of these technologies once these products are approved by the Food and Drug Administration (FDA). National Coverage Determinations (NCDs) are made through an evidence-based process, with multiple opportunities for public participation. Possible NCD outcomes include: coverage; non-coverage; or Coverage with Evidence Development, which is used to cover technologies that have clinical study evidence showing likely promise to improve health outcomes for the Medicare population, but not enough evidence for CMS to confidently cover the item or service without additional data submission requirements. Once a product is approved by the FDA, CMS and our contractors work quickly to determine appropriate Medicare coverage policies. While every product is unique, and some decisions take longer than others, in fiscal year (FY) 2018, we achieved an average time of 6 months from the date of a formal request to the date of publication of the proposed decision memorandum.

The coverage process for innovative technologies also includes collaboration with our colleagues at the FDA. Since 2010, the FDA and CMS have been working in close coordination to improve timely patient access to new and innovative medical products. In 2011, the FDA and CMS introduced the Parallel Review Pilot Program, which established a mechanism for FDA and CMS to simultaneously review the submitted clinical data to decrease the time between FDA's approval of a premarket approval application and the subsequent CMS NCD. The Parallel Review Pilot Program was successful in promoting data sharing and coordination between FDA and CMS and in providing clear communication and expectations for device innovators, and in October 2016, we announced that the Parallel Review Program will be fully implemented and

[2] Available at https://www.healthcare.gov/immigrants/lawfully-present-immigrants/

extended indefinitely. To date, we have finalized two NCDs through the Parallel Review Program. Outside of this formal process, we seek efficiencies in the coverage process by collaborating with our FDA colleagues. For example, as a sponsor's product moves through the FDA's pipeline, we attend FDA meetings and provide guidance on the clinical trials when the device is moved to a pivotal study (i.e., the study used for FDA-approval). The collaboration between CMS and FDA also makes use of interagency personnel temporary reassignments. These allow for integration and cross-training for both agencies and create a culture of collaboration through meaningful interaction.

As required by Congress under section 1869(f)(7) of the Social Security Act, CMS issues an annual Report to Congress on the amount of time it took to complete and implement all NCDs, including those for items, services, or medical devices that were not previously covered, made in the previous fiscal year. Those reports are available at: https://www.cms.gov/Medicare/Coverage/InfoExchange/Reports.

In 2018, CMS accepted four complete, formal requests for NCDs and declined three, consistent with the criteria in the Federal Register notice on the NCO process. In 2018, CMS finalized three NCDs. Some of the NCDs completed during the year are reconsiderations of existing NCDs because CMS responds to new clinical information, professional society recommendations/guidance, or advancements in uses of technologies by reviewing existing NCDs to determine if change is needed. When appropriate, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

In addition, HHS is working to spur innovation and facilitate access to transformative new drugs and devices that are intended to treat serious or life-threatening diseases or conditions for which there are unmet medical needs. CMS finalized an alternative pathway in FY 2020 for new technology add-on payment (NTAP) under the Inpatient Prospective Payment System (IPPS) and pass-through payment status under the Outpatient Prospective Payment System (OPPS) for medical devices that receive the FDA breakthrough device designation for accelerated approval or clearance. CMS also increased the NTAP amount from 50 percent to 65 percent, or for some antimicrobials 75 percent, to more adequately cover the costs, and incentivize use of these new technologies. CMS clarified what it means for a device to meet the substantial clinical improvement criteria necessary to obtain these increased new technology add-on payments. Finally, CMS established a transitional add-on payment adjustment to support the use of new and innovative renal dialysis equipment or supplies furnished by dialysis facilities.

2. **The Protecting Access to Medicare Act of 2014 (PAMA) was intended to reframe Medicare's static payment system for laboratory diagnostic tests under the Clinical Laboratory Fee Schedule (CLFS) to a market-based system by linking Medicare payment rates to ones paid by private payors in the commercial sector. As part of PAMA's implementation, CMS analyzed private-payer data it collected from about 2,000 laboratories to develop new payment rates for individual laboratory tests on the**

CLFS. CMS excluded data from nearly all hospital outreach laboratories and the overwhelming majority of physician office laboratories in setting new payment rates.

- **a. What steps is CMS taking to collect private-payer data from all laboratories required to report under PAMA, including hospital and physician office laboratories?**
- **b. Is CMS working with relevant stakeholders to ensure there is a more transparent and clear process for data collection?**
  - **i. If yes, what specific actions has CMS done or will CMS do to increase transparency?**
  - **ii. If no, why not?**

CMS Response: Prior to implementing these new Medicare rates, CMS was required to collect certain private payer rate data from applicable laboratories to inform the rate setting process. Through notice and comment rulemaking (81 FR 41035), CMS considered stakeholder input in establishing parameters for the collection of the applicable information. In addition to rulemaking, CMS posted press releases and fact sheets on the CMS website describing the changes required by section 2l6(a) of PAMA and its progress in implementing the law. CMS held three national provider calls focused on data reporting and the data collection system. As a result of these efforts, the data reported to CMS during the initial data reporting period captured more than 96 percent of laboratory tests on the CLFS, representing over 96 percent of Medicare's spending on CLFS tests in calendar year 2016. Laboratories from every state, the District of Columbia, and Puerto Rico reported applicable information. To determine if CMS could improve the 96 percent reporting rate without creating significant further burden for laboratories, particularly small laboratories, CMS modeled three additional reporting scenarios to estimate the impact of increasing data reporting.[3] Based on this analysis, CMS determined that additional reporting requirements were not likely to result in a significant change to payment amounts, irrespective of how many additional laboratories reported. However, CMS noted that it would continue to analyze the effect of additional data when setting Medicare payment rates in the future.

In preparation for the data collection period for most tests that ran from January 1, 2019, through June 30, 2019, CMS made two changes to the definition of applicable laboratory in the Medicare Physician Fee Schedule Calendar Year 2019 final rule (83 FR 59671, 60033 and 60074), which CMS believes will lead to an even more robust data collection from which to calculate payment rates for the next CLFS update, as more laboratories may be required to report data. First, the final rule excludes Medicare Advantage plan payments from the total Medicare revenues, the denominator of the Medicare revenues threshold, which CMS believes will result in more types of laboratories qualifying as an applicable laboratory. CMS believes that its previous interpretation of total Medicare revenues, which included Medicare Advantage revenues, may have had the effect of excluding certain laboratories from meeting the majority of Medicare

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

revenues threshold criterion and, therefore, from qualifying as applicable laboratories. In addition, CMS amended the definition to include hospital outreach laboratories that bill Medicare Part B using the CMS-1450 14x Type of Bill.

Regarding the data collected in 2019, as a result of Section 105 of the Further Consolidated Appropriations Act of 2020, CMS delayed the data reporting period for the 2019 data by one year (until 2021). CMS is continuing to evaluate ways to increase data reporting, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory.

The Honorable Janice D. Schakowsky (D-IL)

1. **A July 2019 Government Accountability Office (GAO) report, "Improved Oversight Needed to Better Protect Residents from Abuse," found that the number of nursing home resident abuse citations more than doubled between 2013 and 2017. GAO indicated that one in five nursing homes rated as "above average" and "much above average" by have been cited for abuse in a single year. Despite these findings, in August 2019 you asked Congress for the authority to reduce the frequency of health inspections from every 12 months to every 30 to 36 months for "top-performing" nursing homes.**

    a. **Given that GAO's report suggests that a nursing home's rating or ranking is a poor indicator of nursing home quality, why is CMS seeking to roll back federal law to reduce oversight of "top-performing" facilities?**
    b. **Your request, if granted, means that resident and family complaint surveys will become the primary driver of inspections within a three-year standard inspection cycle. Why do you believe it is appropriate to shift the burden of nursing home oversight from CMS to residents and families?**

CMS Response: Protecting the health and safety of nursing home residents is one of the most important responsibilities CMS has. Today, there are over 15,000 nursing homes in America, and CMS is responsible for monitoring all of them. Over the past few years, there has been an increase in the volume and severity of complaints that need to be investigated, in addition to rising survey costs. However, the allocated funds from which CMS funds all of our survey and certification activities has remained flat for over five years. The President's Fiscal Year 2020 Budget requests a $45 million increase from the previous year for Survey and Certification. The Budget also includes a legislative proposal that would give CMS the ability to focus our resources more effectively by granting us the authority to transition to a risk-based survey model for nursing homes. CMS currently uses a risk-based approach for other facility types, such as ambulatory surgical centers and outpatient physical therapy centers, based on externally identified risk for abuse or fraud, prevalence of adverse events, and available resources. Under this proposal, top performing facilities would be surveyed every 30 months, with no more than 36 months between surveys of any single facility—this would allow CMS to focus more time and resources overseeing nursing homes that are poor performers and on responding to

complaints from residents and family members. To determine which facilities would be eligible for reduced survey frequency, CMS would develop a risk-methodology, considering factors such as prior survey performance, level of staffing in the nursing home, and other quality measures such as five star ratings in the Five Star Quality Ratings Program listed on Nursing Home Compare. Importantly, we would also continue to inspect all facilities in response to complaints, giving providers incentive to continuously monitor quality. While high performing facilities have fewer instances of abuse or neglect, we know they can occur at both low and high performing facilities, and we are committed to holding all facilities accountable for the quality of care they provide.

2. **Nursing homes that voluntarily participate in the Medicare and Medicaid programs must adhere to standards set out in the federal Nursing Home Reform Act and its implementing regulations. In October 2016, CMS published a final rule revising the Medicare and Medicaid Requirements of Participation (Requirements) for nursing homes to improve their quality of care and residents' quality of life. Shortly after, in December 2016, the American Health Care Association and National Center for Assisted Living (AHCA/NCAL), a leading nursing home industry trade association, sent a letter to then President-elect Donald Trump asking for regulatory relief. In July 2019, CMS issued proposed rulemaking that would partially or completely roll back critical Requirements, including those dealing with antipsychotic drugs, infection prevention, and grievances.**

    a. **Does the proposed rollback of the Requirements violate this provision of federal law?**
    b. **If not, how does the proposed rollback of these Requirements protect residents' health, safety, welfare, and rights?**
    c. **If CMS is going to roll back federal oversight, what steps is your agency taking to improve performance and accountability of state oversight agencies, as well as the Regional Offices charged with overseeing them, to ensure that residents are protected?**

CMS Response: After a thorough review of our long-term care facility requirements, we proposed a rule (84 FR 34718) on July 18, 2019, that would simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare for their residents. We believe that these proposals balance resident safety and quality of care with providing regulatory relief for facilities.

That being said, we are not rolling back long-term care facility protections. For example, when we reviewed how Regional Offices were imposing civil money penalties (CMPs), we found that states were issuing different CMP amounts for the same type of noncompliance. In an effort to standardize this calculation across the country, CMS revised the analytic tool used to determine CMPs in July 2017.

Furthermore, CMS is continuing additional efforts to address inappropriate prescribing and improve the quality of life for nursing home residents, including the National Partnership to Improve Dementia Care. The Partnership promotes a multidimensional approach that includes public reporting, state-based coalitions, research, training, and revised surveyor guidance. We believe that having the same requirements for all psychotropic drugs will simplify the survey process and reduce improper deficiency citations, as well as remove potential obstacles for mental health professionals to provide quality care for residents.

3. **In 2011, the U.S. Department of Health and Human Services (HHS) Inspector General identified the persistent, widespread use of antipsychotic drugs as a threat about which "the Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged." While there has been moderate progress, much more still needs to be done. Approximately 15 percent of all nursing home residents nationwide are still being administered off-label antipsychotic drugs. Too often, these potentially deadly drugs are used to treat the behavioral symptoms of dementia or as a form of chemical restraint to compensate for inadequate staffing.**

    a. **What is CMS doing in respect to promised enforcement of longstanding requirements prohibiting the use of unnecessary drugs and chemical restraints?**
    b. **Rather than rolling back standards of care for antipsychotic drugs through the July 2019 proposed rule for Requirements of Participation, why didn't CMS propose additional resident protections, such as requiring written informed consent for antipsychotic drugs?**

CMS Response: At CMS, we share your concern about the inappropriate prescribing of antipsychotic drugs for nursing home residents. Through our National Partnership to Improve Dementia Care in Nursing Homes, CMS collaborates with Federal and state agencies, nursing homes, other providers, advocacy groups, and care partners to optimize the quality of care and quality of life for residents by reducing the use of antipsychotic medications and enhancing the use of non-pharmacologic approaches and person-centered dementia care practices.

Between 2011 and the third quarter of 2018, the national prevalence of antipsychotic medication use among long-stay nursing home residents decreased by 38.9 percent to a national prevalence of 14.6 percent, and approximately 1,500 facilities were identified as "late adopters" in December 2017. A facility is a late adopter if it has not improved their antipsychotic medication utilization rates for long-stay nursing home residents since 2011. In March 2019, we announced enhanced oversight and enforcement efforts for these late adopters. CMS and the state survey agencies will be closely monitoring these late adopters to ensure that they achieve and continue to maintain substantial compliance in these areas. In addition to this new enforcement approach, CMS is also engaging with corporate chains that own or operate significant numbers of nursing homes identified as late adopters. I personally called the CEOs of several nursing home chains with late adopter facilities to call their attention to this issue. CMS will be closely monitoring all

these late adopter facilities to ensure that they achieve and continue to maintain substantial compliance in these areas.

We believe that having the same requirements for all such drugs will simplify the survey process and reduce improper deficiency citations, as well as remove potential obstacles for mental health professionals to provide quality care for residents. These changes, if finalized, would provide the flexibility that facilities and providers need to assure that they can care for their residents without excessive administrative burden.

The Honorable Joseph P. Kennedy III (D-MA)

1. **Cardiac Computed Tomography (CT) is a non-invasive test that can accurately identify the amount and severity of coronary artery disease. Due to its ability to more accurately identify plaque in the heart arteries, cardiac CTs to evaluate patients with chest pain are associated with lower rate of subsequent heart attacks and heart-attack related deaths. In selected cases when there are narrowings in the heart arteries, CT-Fractional Flow Reserve (CT-FFR) is a test which uses CT data to non-invasively estimate the severity of blockages detected by cardiac CT, and thus inform clinicians if the use of coronary stents or bypass surgery may be beneficial, or not. Prior to CT-FFR, the method to detect this was invasive.**

   Providers who currently use CT-FFR tests in hospital outpatient settings are reimbursed using the CMS New Technology Ambulatory Payment Classification (APC) from 2018. This has enabled them to offer the service broadly to Medicare beneficiaries.

   In CMS's OPPS Proposed Rulemaking that will take effect on January 1, 2020, you cut the reimbursement rate for CT-FFR by about half. In office-based settings reimbursement for CT-FFR has also been a small fraction of the 2018 APC rate. Hospitals and physicians simply cannot afford to offer a test for which the reimbursement is far lower than the cost of providing the test, and patients will instead undergo more costly and sometimes invasive tests that may not be as useful in detecting and managing heart disease.

   Your proposal, based on an analysis of only 78 claims, would deprive Medicare beneficiaries of the manifest benefits of this new technology.

   Wouldn't it be better to stipulate a fair payment in the office-based setting and leave the 2018 New Technology APC in place long enough for hospitals and physicians to have the opportunity to get it established rather than rely on a statistically insignificant sample size and frustrate the adoption of this better, less invasive and more cost-effective pathway for the benefit of Medicare beneficiaries?

CMS Response: For new technology items and services that meet specific criteria, Medicare can make special payments under the Outpatient Prospective Payment System (OPPS), allowing us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Guidance describing the process and information required for applications requesting a New Technology Ambulatory Payment Classification (APC) assignment is available on the CMS website.[4]

The developer of fractional flow reserve derived from computed tomography (FFRCT) first submitted an application for the procedure to be given a temporary procedure code and assigned to a New Technology APC in March 2016. According to the FDA, FFRCT uses post-processing software to create "a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images."[5] FFRCT is performed outside the outpatient hospital setting by HeartFlow, which uses proprietary software to conduct the analysis. CMS denied the developer's application because we considered the FFRCT procedure to be an image guidance, processing, supervision, or interpretation service whose payment should be packaged into the payment for the related computed tomography service, in accordance with our regulations at 42 CFR 419.2(b)(13). The developer then filed a New Technology APC reconsideration request in March 2017 asking that CMS reverse its denial of the developer's application to have the FFRCT assigned to a New Technology APC. We reviewed the reconsideration request and denied the request for the same reason as we did in March 2016.

In response to the OPPS/Ambulatory Surgical Center Calendar Year (CY) 2018 Proposed Rule, some commenters, including the developer, stated that CMS did not properly interpret the regulation at 42 CFR 419.2(b)(13) in its previous decisions to deny the FFRCT application and reconsideration request to receive separate payment in a New Technology APC. After reviewing the public comments, we agreed with commenters that the FFRCT service is not image guidance or supervision because FFRCT does not produce images, does not appear to be a supportive guidance service that aids in the performance of an independent procedure, and, unlike typical supervision services, is not generally reported when the initial image is acquired. Accordingly, in the Final Rule, we assigned the FFRCT service, as described by CPT code 0503T to a New Technology (APC) 1516 for CY 2018, with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. This payment remained unchanged for CY 2019 because we did not yet have sufficient claims data to assess the FFRCT service's APC assignment.[6]

To determine an appropriate payment rate for CY 2020, CMS conducted an analysis of the CY 2018 claims data available. We found that over 840 claims had been submitted for payment for CPT code 0503T during CY 2018, and the estimated geometric mean cost was $788.19, or

[4] Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/newtechapc.pdf
[5] Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130045.pdf
[6] Available at: https://www.federalregister.gov/documents/2018/11/21/2018-24243/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center

roughly $660 lower than the payment rate of $1,450.50. After consideration of our analysis and the public comments we received, we utilized our new technology low-volume payment policy to set the payment rate for the HeartFlow service CPT code 0503T based on the arithmetic mean for the procedure, which was $960.12. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 with a payment rate of $950.50 to ensure the payment rate better reflects the cost for the service.

The Honorable Ann M. Kuster (D-NH)

1. **While I appreciate recent efforts by the Administration to address unique challenges facing rural hospitals, as you know, the closure rates for these vital sources of care are increasing at a concerning rate. CMS and other agencies within the Department of Health and Human Services have sought out various ways to help support the health services needs of rural communities, but more needs to be done.**

   Each year, CMS recalibrates MS-DRG weights. Each year, CMS also includes the estimated impact of these changes in MS-DRG weights in the notice of the proposed update to the Inpatient Prospective Payment System (IPPS). Rural hospitals generally, and hospitals designated as Rural Referral Centers (RRCs), Sole Community Hospitals (SCHs) and Medicare-dependent Hospitals (MDHs) in particular, are distinctly and disproportionately negatively impacted by these recalibrations. While the trend was mixed in FY 2020, that is not the case for all of these rural cohorts, and there appears to be something systemic that bears examination and possible remediation.

   What steps is CMS taking to examine this phenomenon and consider making an adjustment, if deemed appropriate?

CMS Response: In general, Medicare pays for hospital inpatient stays by using the Inpatient Prospective Payment System (IPPS) to pay a pre-determined, specific rate for each hospital discharge. CMS categorizes each discharge into one of over 700 Medicare Severity Diagnosis-Related Groups (MS-DRGs), and determines a "relative weight" for each MS-DRG that adjusts payments based on the average resources to care for cases in that MS-DRG as compared to the average resources to care for cases in all MS-DRGs. For example, the relative weight for MS-DRG 002 (heart transplant) is higher than the relative weight for MS-DRG 122 (acute eye infection), and Medicare will pay a higher amount for beneficiary discharges assigned to this MS-DRG.

Under statute, CMS is required to adjust the MS-DRG classifications and relative weights at least annually.[7] These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. CMS makes these changes as part of its annual IPPS rulemaking. We take the comments we receive as part of this

[7] Section 1886(d)(4)(C) of the Social Security Act

rulemaking—along with other provider feedback we receive—very seriously to inform our decision-making as we work to pay hospitals an appropriate amount.

We anticipate that changes to the MS-DRGs and relative weights finalized in our FY 2020 IPPS Final Rule will result in an overall 0.0 percent change in payments for hospitals.[8] As discussed in the FY 2021 IPPS Proposed Rule, proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments for hospitals.[9] Hospitals that generally treat cases in higher severity MS-DRGs will experience a slight increase in their payments, while hospitals that generally treat fewer of these cases will experience a decrease in their payments under the relative weights. We recognize the critical services provided by rural hospitals, including Rural Referral Centers, Sole Community Hospitals, and Medicare-dependent Hospitals. The Trump Administration has placed an unprecedented priority on improving the health of Americans living in rural areas, and last year, CMS furthered this commitment by introducing the agency's first Rural Health Strategy.[10] We will continue to monitor the impact our policies have on providers in rural areas, and we look forward to continuing our work with Congress, providers, and other stakeholders to improve our programs.

The Honorable Yvette D. Clarke (D-NY)

1. **CMMI has been operating the Ends Stage Renal Disease Seamless Care Organization (ESCO) program for the last few years, and there is increased concern from providers participating in the program that CMMI continues to make decisions in a black box. I have heard from those in my state participating in the program that CMMI does not share important information on methodology changes or provide accurate reports to participants. How can you expect providers to be successful when they do not fully understand the methodology being used to gauge performance?**

CMS Response: Between Performance Year (PY) 1 (2015-2016) and PY2 (2017) of the Innovation Center's Comprehensive End Stage Renal Disease (ESRD) Care Model, the Innovation Center corrected several errors and made updates to the methodology for the Model.

These updates were to improve accuracy and respond directly to ESRD Seamless Care Organization feedback and were communicated both in writing and via webinar.[11] The Innovation Center will continue to make every effort to be transparent and responsive to the concerns of these and other organizations.

[8] Final Rule available at: https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[9] Proposed Rule available at: https://www.federalregister.gov/documents/2020/05/29/2020-10122/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[10] CMS Rural Health Strategy available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf
[11] Available at https://innovation.cms.gov/innovation-models/comprehensive-esrd-care/archived-materials

2. **Providers who have participated in many of the CMMI programs, such as ACOs and ESCOs, have reported frustration with a lack of transparency on the part of the innovation center. As CMMI looks to implement broad, mandatory demonstrations such as the radiation oncology model and the kidney model, can you please provide specific details as to how these programs will be better implemented to ensure providers have the information they need to perform in these demonstrations?**

CMS Response: CMS is committed to unleashing innovation within the health care sector, and the Innovation Center plays a key role in our efforts to continue shifting toward a value-based system that tracks and rewards improvements in quality. The Innovation Center's authority allows CMS to implement time-limited models that give us a better understanding of specific delivery system reform methods before they are potentially implemented nationwide.

We are committed to transparency and stakeholder input in Innovation Center models. The statute requires the Innovation Center to consult representatives of relevant federal agencies and clinical and analytical experts with expertise in medicine and health care management and to use open door forums or other mechanisms to seek input from interested parties.[12] Consistent with this requirement, we want to ensure that our policy efforts are guided by the real experience of clinicians on the frontlines. Accordingly, since its inception, the Innovation Center has consulted and worked with stakeholders across the country, other federal agencies, and other operating divisions within the Department of Health and Human Services to identify promising new payment and service delivery models and help design new models. The Innovation Center invites and seeks input on issues in health care payment and delivery through forums that are open to all members of the public, including Requests for Information, Notice and Comment Rulemaking, and "open door" phone conferences.

Currently, participation in Innovation Center models is voluntary on the part of health care providers, except in the case of a limited number of mandatory models. In the latter cases, participation by providers is mandatory and the Innovation Center has proposed and finalized these mandatory models through Notice and Comment rulemaking.

Any time we launch a model, we strive to ensure that stakeholders are given the tools they need for successful participation. The Innovation Center conducts numerous activities to continually update innovators in the field on new funding and learning opportunities. In addition to publishing press releases, fact sheets, and other informational resources online, the Innovation Center conducts numerous webinars and public listening sessions to provide model details, clarify application and participation requirements, and answer questions from stakeholders.[13]

[12] Section 1115A(a)(3) of the Social Security Act
[13] Resources and information about upcoming webinars available at: https://innovation.cms.gov/index.html

The Honorable Scott H. Peters (D-CA)

1. **Administrator Verma, in light of the extensive research, regulations, and interpretive guidance by your agency confirming the dangers of opioid-induced respiratory depression and the need for vigilant patient monitoring, I am concerned about CMS's apparent lack of oversight.**

    a. **Currently, does CMS recommend continuous physiological electronic monitoring for all patients taking opioids in the hospital?**
        i. **If not, why is continuous monitoring not recommended by CMS?**
        ii. **If so, does CMS enforce the mandatory use of continuous monitoring at all hospitals participating in Medicare?**
    b. **CMS guidelines state that patients receiving opioids in the hospital require "vigilant" monitoring. What exactly does "vigilant" monitoring mean?**
    c. **Do you interpret current CMS regulations and guidance to require that certain high-risk patients taking opioids in the hospital be continuously monitored?**
    d. **How does CMS ensure that hospitals participating in Medicare, and therefore receiving taxpayer-funded reimbursement, are "vigilantly" monitoring patients taking opioids?**
    e. **Can you provide documentation of CMS Survey Procedures and oversight regarding patient risk assessments and monitoring to prevent opioid-induced respiratory depression?**
    f. **If a hospital is not compliant with CMS guidance regarding the monitoring of patients taking opioids in the hospital, what is the consequence to those healthcare facilities?**
    g. **Currently, deaths caused by opioid-induced respiratory depression are underreported, and the secondary cause of death (i.e., heart attack or pneumonia) is more commonly listed as the official cause of death. According to a study published by the American Medical Association, "the focus on drug overdose may underestimate the harms of opioid analgesics. Opioids can cause or exacerbate sleep-disordered breathing, potentially increasing the risk of adverse cardiovascular events. Opioids also have adverse psychomotor, endocrine, gastrointestinal, and immunologic effects."**

        Does CMS keep track of the number of deaths caused by opioid-induced respiratory depression for patients receiving care under the programs administered by CMS?

CMS Response: CMS expects all hospitals participating in Medicare to meet CMS Hospital Conditions of Participation at all times, including numerous requirements regarding the preparation and administration of drugs. Under the survey guidance used to enforce the CMS Hospital Conditions of Participation, patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification

of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;
- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients' medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or drug-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. Adverse patient reactions require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient.

An example of vigilant post-medication administration monitoring in the case of a high alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Some medications that are often used to control pain may also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur.

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication.

Hospitals are surveyed on a regular basis to verify they are meeting the Conditions of Participation, and compliance surveys may be conducted at any time. Our survey guidelines include a requirement for surveyors to observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed, such as making sure patients who are at higher risk and/or receiving high-alert medications are monitored for adverse effects. When surveyors identify noncompliance with federal Conditions of Participation and standards, they document this for the facility. To continue to participate in Medicare and Medicaid, the hospital is required to address identified issues and develop a corrective action plan. Failure to come into compliance will result in a hospital's termination from the Medicare program.

2. **My colleagues Reps. Danny Davis (D-IL) and Kenny Marchant (R-TX) have introduced The Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, H.R. 4100. The bipartisan DISARM Act will improve access to innovative antimicrobial drugs by leveling the playing field for new products through changes to the bundled Medicare inpatient payment for certain antimicrobials to treat serious or life-threatening infections in the inpatient setting. The changes will allow physicians to make the best clinical treatment decisions for their patients and help to stabilize the very tenuous situation innovators currently face. The DISARM Act will also improve critical stewardship and surveillance measures to improve antimicrobial use and resistance reporting and facilitate the appropriate use of novel products.**

   Does CMS support the DISARM legislation?

CMS Response: CMS is committed to unleashing medical innovation, and this Administration is leading the way to improve incentives for innovation in critical areas, including the ongoing antimicrobial resistance public health crisis. CMS is always willing to work with Congress to improve our programs, including through providing technical assistance on proposed legislation.

In addition, CMS has already taken specific policy steps to reform antibiotic payment. In the Inpatient Prospective Payment System final rule for FY 2020, CMS finalized a number of changes in payment policy to help secure beneficiaries' access to these medications. For example, we finalized a new technology add-on payment pathway for eligible antimicrobial products and increased the add-on payment percentage from 50 to 75 percent for these products. CMS also made changes to the severity level designations for Medicare diagnosis codes for antimicrobial resistance to better reflect the resources needed to care for patients who develop antimicrobial resistance. By increasing payments to hospitals treating beneficiaries with antimicrobial resistance, our policy will create the financial flexibility for physicians to prescribe the appropriate new antibiotics without imposing an additional fiscal burden upon hospitals.

3. **Several of our colleagues have introduced legislation – the Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 (H.R. 3772) – which would establish separate payment for precision, diagnostic radiopharmaceuticals. This legislation would address the problem of beneficiaries not receiving access to diagnostic imaging because of a reimbursement payment anomaly, under which the Medicare program treats diagnostic radiopharmaceuticals as supplies and not as drugs.**

   Given the negative impact of this payment policy on beneficiary access to critical precision diagnostic tools, please explain CMS's rationale for adhering to this policy.

CMS Response: In the CY 2008 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS finalized the policy to provide packaged payment for diagnostic radiopharmaceuticals. [14] We believe that it is most appropriate to package payment for some radiopharmaceuticals, specifically diagnostic radiopharmaceuticals, into the payment for diagnostic nuclear medicine procedures. Diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the independent procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

We recognize that radiopharmaceuticals are specialized products that have unique costs associated with them. However, we believe that the costs should be reflected in the charges that hospitals set for them and in the cost report where the full costs of the services are carried. Therefore, the costs will be calculated like any other OPPS cost and packaged into the total cost of the nuclear medicine service to which they are an integral part and will be the basis for the payment rate for the nuclear medicine service in the same way that other packaged costs contribute to the payment rate for the services to which they are an integral part. We believe that packaging encourages hospitals to use the most cost efficient diagnostic radiopharmaceutical products that are clinically appropriate, and that hospitals will continue to provide care that is aligned with the best interests of the patient.

4. **On October 17th a Federal court ruled that CMS "exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics," and on October 21st the judge ordered CMS to reverse these cuts and pay hospitals backpay for reimbursements paid out during the time the unlawful rule was in place.**

   a. **When will CMS comply with the court order to restore payment rates to 2018 levels?**

[14] Available here: https://www.govinfo.gov/content/pkg/FR-2007-11-27/pdf/07-5507.pdf

b. When will CMS comply with the court order to provide backpay to providers for the time the unlawful rule was in place?
c. How will CMS ensure that future reimbursement policies actually help, rather than undermine, the ability of Critical Access Hospitals and Sole Community Hospitals to continue to provide essential medical care in already underserved communities?
d. If CMS intends to move forward with new rulemaking, how will you ensure compliance with the judge's ruling and statutory requirements outlined in the Bipartisan Budget Act of 2015 (Public Law 114-74) and the 21st Century Cures Act (Public Law no. 114-255) that explicitly exempt existing off-campus hospital clinics from future cuts to reimbursement based on their physical distance from the hospital's main campus?

CMS Response: CMS recognizes the many obstacles that rural health care providers face, and our rural health strategy applies a rural lens to the work of CMS to improve access to care through provider engagement and support, expand access to innovative technologies, empower patients in rural areas to make healthcare decisions, and leverage partnerships to improve health outcomes. We look forward to continuing our work with Congress, providers, and other stakeholders to ensure Americans in rural area have access to the health care services they need.

On November 1, 2019, CMS released the calendar year (CY) 2020 OPPS final rule with comment period. In last year's final rule for CY 2019, we adopted a method to reduce unnecessary utilization in outpatient services by eliminating payment differences between certain outpatient sites of service.[15] In this year's final rule for CY 2020, we stated that we are completing the two-year phase-in of this policy by addressing payments for clinic visits furnished in the off-campus hospital outpatient setting. We explained in the final rule that this change would result in lower copayments for beneficiaries and savings for the Medicare program and taxpayers of estimated $800 million for 2020.

On December 12, 2019, we announced that we installed a revised Hospital Outpatient Prospective System Pricer to update the rates being applied to claim lines for 2019. The revised Pricer went into product on November 4, 2019, and applies to claims with a line item date of service of January 1, 2019, and after. Starting January 1, 2020, and over the next few months, the Medicare Administrative Contractors will automatically reprocess 2019 claims paid at the reduced rate, with no provider action needed. Also on December 12, 2019, we filed a notice appealing the District Court's decision to the United States Court of Appeals for the District of Columbia Circuit, and the Court of Appeals heard argument on April 17, 2020.

On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, finding that the regulation was based on a reasonable interpretation of the

[15] Final Rule available at: https://www.federalregister.gov/documents/2018/11/21/2018-24243/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center

Department's statutory authority to adopt volume-control methods. CMS is reviewing this recent judgment, including any and all actions necessary to implement the decision of the D.C. Circuit.

5. **Rural communities face many barriers to accessing high quality health care, and they have been disproportionally affected by the opioid epidemic. Critical Access Hospitals (CAHs) are well positioned in rural communities to provide much-needed services, and they rely on cost-based reimbursement to maintain high-quality care. Unfortunately, many of the most critical services needed to combat the opioid epidemic, including opioid use disorder treatment, other addiction services, and mental and behavioral health services, are not eligible for cost-based reimbursement which presents a significant financial barrier for most CAHs to provide these services. Further, if a CAH is able to provide these services at the reduced reimbursement rate, they are further penalized by a reduction in their overall CMS reimbursement for overhead costs associated with adding these services. As a result of these policies, patients are forced to rely on the emergency room to receive these critical addiction and mental health services. Not only is this system not cost-effective, it also produces worse outcomes for patients.**

    a. **Recognizing the important role that CAHs play in the fight against the opioid epidemic in communities with the greatest need, why are treatments for addiction and other behavioral and mental health services not eligible for cost-based reimbursement?**
    b. **For Fiscal Years 2010-2019, how much has CMS spent annually on reimbursements to hospitals for addiction, behavioral and mental health services provided in an emergency setting?**
    c. **How does CMS determine reimbursement rates for overhead costs incurred by CAHs?**
    d. **Some CAHs have reported that CMS will not fully reimburse overhead costs for services which are not eligible for cost-based reimbursement. If this is the case, please explain the rationale and identify the statutory requirements that support this policy.**

CMS Response: Approximately 60 million people live in rural areas across the United States – including millions of Medicare and Medicaid beneficiaries. CMS recognizes the many obstacles that rural Americans face when accessing healthcare services, including a fragmented healthcare delivery system, stretched and diminishing rural health workforce, unaffordability of insurance, and lack of access to specialty services and providers. CMS launched the agency's first Rural Health Strategy in May 2018 to help improve access to high quality, affordable healthcare in rural communities. The strategy is intended to provide a proactive and strategic focus on healthcare issues across rural America to ensure the nearly one in five individuals who live in these areas have access to care that meets their needs.

Critical access hospitals (CAHs) play a vital role in increasing access to important health care services in rural areas. Unlike other acute care hospitals, CAHs represent a separate provider type with their own Medicare Conditions of Participation as well as a separate payment method under Medicare. CAH services are typically paid at 101 percent of the reasonable costs. Section 1820(c)(2)(E) of the Social Security Act allows CAHs to establish a distinct part psychiatric unit, where services are paid for under the Medicare Inpatient Facility Prospective Payment System. Section 1820(c)(2)(E) of the Social Security Act also allows CAHs to establish a distinct part rehabilitation unit, where services are paid for under the Medicare Inpatient Rehabilitation Facility Prospective Payment System. All CAHs should consider starting buprenorphine therapy during hospitalizations to treat patients with opioid use disorder when clinically appropriate, similar to other hospitals.

CMS has worked with state Medicaid programs to ensure they have the tools they need to address the opioid crisis. As an example, to date, CMS has approved 27 section 1115 demonstrations, which have permitted states to expand their full continuum of care for opioid use disorder and substance use disorder treatment.

The Honorable Brett Guthrie (R-KY)

1. **In the President's Executive Order, "Protecting and Improving Medicare for Our Nation's Seniors," there is language to make it easier for innovative products to gain Medicare coverage, so that patients can have easier access to new, exciting innovation.**

    a. **How long, after U.S. Food and Drug Administration (FDA) approval, does it typically take to open a national coverage decision, and then how long until the agency makes a final judgment on Medicare coverage?**
    b. **Does the agency have a problem with getting coverage for FDA approved products?**
    c. **Recently I have been notified that several National Coverage Decisions (NCDs) applications have been delayed and not processed in a timely manner. This has put several new advances in a permanent holding pattern within your agency. I am concerned that this practice is unduly and unfairly delaying the availability of potentially life-saving tests and tools from the marketplace and is outside the both the letter and the spirit of the NCD process. Are you aware of these delays? Does the Centers for Medicare and Medicaid Services (CMS) plan to address these delays?**
    d. **What other tools could you use from Congress in order to help get innovative products to patients faster, particularly ones that have already been approved as safe and efficacious by FDA?**

CMS Response: CMS uses multiple pathways to provide Medicare coverage of innovative technologies to beneficiaries, and we strive to provide fast coverage of these technologies once these products are approved by the Food and Drug Administration (FDA). National Coverage

Determinations (NCDs) are made through an evidence-based process, with multiple opportunities for public participation. Possible NCD outcomes include: coverage; non-coverage; or Coverage with Evidence Development, which is used to cover technologies that have clinical study evidence showing likely promise to improve health outcomes for the Medicare population, but not enough evidence for CMS to confidently cover the item or service without additional data submission requirements. Once a product is approved by the FDA, CMS and our contractors work quickly to determine appropriate Medicare coverage policies. While every product is unique, and some decisions take longer than others, in fiscal year (FY) 2018, we achieved an average time of 6 months from the date of a formal request to the date of publication of the proposed decision memorandum.

The coverage process for innovative technologies also includes collaboration with our colleagues at the FDA. Since 2010, the FDA and CMS have been working in close coordination to improve timely patient access to new and innovative medical products. In 2011, the FDA and CMS introduced the Parallel Review Pilot Program, which established a mechanism for FDA and CMS to simultaneously review the submitted clinical data to decrease the time between FDA's approval of a premarket approval application and the subsequent CMS NCD. The Parallel Review Pilot Program was successful in promoting data sharing and coordination between FDA and CMS and in providing clear communication and expectations for device innovators, and in October 2016, we announced that the Parallel Review Program will be fully implemented and extended indefinitely. To date, we have finalized two NCDs through the Parallel Review Program. Outside of this formal process, we seek efficiencies in the coverage process by collaborating with our FDA colleagues. For example, as a sponsor's product moves through the FDA's pipeline, we attend FDA meetings and provide guidance on the clinical trials when the device is moved to a pivotal study (i.e., the study used for FDA-approval). The collaboration between CMS and FDA also makes use of interagency personnel temporary reassignments. These allow for integration and cross-training for both agencies and create a culture of collaboration through meaningful interaction.

As required by Congress under section 1869(f)(7) of the Social Security Act, CMS issues an annual Report to Congress on the amount of time it took to complete and implement all NCDs, including those for items, services, or medical devices that were not previously covered, made in the previous fiscal year. Those reports are available at: https://www.cms.gov/Medicare/Coverage/InfoExchange/Reports.

In 2018, CMS accepted four complete, formal requests for NCDs and declined three, consistent with the criteria in the Federal Register notice on the NCO process. In 2018, CMS finalized three NCDs. Some of the NCDs completed during the year are reconsiderations of existing NCDs because CMS responds to new clinical information, professional society recommendations/guidance, or advancements in uses of technologies by reviewing existing NCDs to determine if change is needed. When appropriate, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

In addition, HHS is working to spur innovation and facilitate access to transformative new drugs and devices that are intended to treat serious or life-threatening diseases or conditions for which there are unmet medical needs. CMS finalized an alternative pathway in FY 2020 for new technology add-on payment (NTAP) under the Inpatient Prospective Payment System (IPPS) and pass-through payment status under the Outpatient Prospective Payment System (OPPS) for medical devices that receive the FDA breakthrough device designation for accelerated approval or clearance. CMS also increased the NTAP amount from 50 percent to 65 percent, or for some antimicrobials 75 percent, to more adequately cover the costs, and incentivize use of these new technologies. CMS clarified what it means for a device to meet the substantial clinical improvement criteria necessary to obtain these increased new technology add-on payments. Finally, CMS established a transitional add-on payment adjustment to support the use of new and innovative renal dialysis equipment or supplies furnished by dialysis facilities.

2. The Center for Medicare and Medicaid Innovation (CMMI) has great flexibility in design and implementation of its demonstration programs.

- **a. As part of this flexibility, does CMMI have the authority to engage with participating providers throughout the course of the demonstrations, thereby enabling CMMI to openly discuss changes that may be needed based on new information or unintended consequences that arise throughout the course of the demonstration? Are there any restrictions on CMMI's authority?**
- **b. If CMMI has this authority, from speaking with providers participating in current demonstrations at CMMI, the innovation center has not seemed willing to engage in these conversations or make changes to the programs. Given the flexibility that CMMI has, would you consider allowing open conversation and potential model changes as an element of future demonstrations?**

CMS Response: CMS is committed to unleashing innovation within the health care sector, and the Innovation Center plays a key role in our efforts to continue shifting towards a value-based system that tracks and rewards improvements in quality. The Innovation Center's authority allows CMS to implement time-limited models that give us a better understanding of specific delivery system reform methods before they are potentially implemented nationwide.

Consistent with the statutory requirement that the Innovation Center consult with other federal agencies and certain other experts in carrying out its duties, we are committed to transparency and stakeholder input in Innovation Center models, and we want to ensure that our policy efforts are guided by the real experience of clinicians on the frontlines. Since its inception, the Innovation Center has consulted and worked with stakeholders across the country, other federal agencies, and other operating divisions within the Department of Health and Human Services to identify promising new payment and service delivery models and help design new models. Ideas for new models come from internal and external stakeholders, including obtaining feedback from Congress, patient groups, experts in the field, the Physician-Focused Payment Model Technical Advisory Committee, and other agencies.

In addition to seeking extensive feedback used to inform model development, the Innovation Center engages with stakeholders throughout model implementation to discuss lessons learned and examine ways to improve our model tests. For example, in January 2019, CMS announced changes to update the Medicare Advantage Value-based Insurance Design Model to incorporate stakeholder feedback gathered from the September 2017 New Direction Request for Information[16] and follow-up discussions, as well as lessons learned from the model's first and second performance years.

During model implementation, data on performance and outcomes measures are collected and reviewed at prescribed intervals. CMS conducts independent evaluations, based on quantitative and qualitative data, of Innovation Center models and releases those findings publicly. These reports provide stakeholders with information on the impact of the model as a whole on health care expenditures and utilization, health outcomes, and, where feasible, beneficiary and health care provider experiences. Often the reports also provide site-specific results.

To evaluate models, the Innovation Center generally uses independent evaluators to routinely and rigorously assess the impact of each model on care quality and expenditures. The evaluations include advanced statistical methods and carefully defined and selected comparison groups, as appropriate, to ensure that models deemed to be successful represent true opportunities for high-value investments of taxpayer dollars. Central to this evaluation approach is the recognition that evaluators must not only assess results, but also understand the context that generates those results. For each model, the Innovation Center tailors the collection of qualitative information to the needs of the model, with the goal of integrating the qualitative information with quantitative findings in order to best identify and understand the impact of the model test. Every Innovation Center model also includes a plan of action to ensure that the lessons learned and best practices identified during the test can be spread as widely and effectively as possible to support improvement for both public programs and the health care system at large.

CMS is always looking for ways to improve our programs, including the models we implement through the Innovation Center, and we will continue to engage with stakeholders to help foster the design and implementation of potential new payment and service delivery models.

3. Non-opioid based therapies are a critical component in helping address current and future cases of opioid use disorder

a. To further allow access for patients, will CMS consider issuing guidance to ensure states are complying with the SUPPORT for Patients and Communities Act's (SUPPORT Act's) Medicaid provisions? Specifically, will CMS issue guidance to underscore that all state Medicaid programs must cover all FDA

[16] The Centers for Medicare & Medicaid Services: Innovation Center New Direction Request for Information is available at: https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.

approved drugs to treat opioid-use disorder, including non-opioid based therapies?

b. In addition, what steps will CMS take to ensure state Medicaid programs, Medicare Advantage, and Medicare Part D plans are not inappropriately using prior authorization to delay and effectively deny access to non-opioid based therapies?

CMS Response: As of September 2019, CMS has implemented 11 sections of the SUPPORT Act. These include issuing Medicaid non-opioid pain guidance and awarding $50 million in planning grants to 15 states through a demonstration project to increase substance use provider capacity in the Medicaid program as required by section 1003 of the SUPPORT Act. Also, CMS has worked with state Medicaid programs to ensure they have the tools they need to address the opioid crisis. As an example, to date, CMS has approved 27 state Medicaid 1115 demonstrations, which have permitted states to expand their full continuum of care for opioid use disorder and other substance use disorder treatment by authorizing Medicaid expenditures for services furnished to beneficiaries who are short term residents in an institution for mental diseases primarily to receive substance use disorder treatment.

Medicare Advantage (MA) rules allow plans to use reasonable utilization management techniques, such as prior authorization, to ensure that furnished services are both medically necessary and appropriate. However, prior authorization should not create an unnecessary barrier to needed care, and plans are required to make timely decisions regarding coverage of services. To safeguard beneficiary access to services, MA organizations must make timely and expeditious coverage decisions in accordance with time frames stated in regulations. MA plans are also required to disclose any coverage restrictions, such as prior authorization requirements, to providers and enrollees. In addition, in order to ensure that MA plans do not restrict access to certain services, CMS has established a robust appeals process for beneficiaries enrolled in MA plans. CMS carefully monitors enrollee access to services through plan audits, review of beneficiary appeals, and complaints from beneficiaries or other interested parties.

Further, as noted in the CY 2020 Medicare Advantage Rate Announcement, CMS encourages MA organizations to consider Part C benefit designs for supplemental benefits that address non-opioid pain management and complementary and integrative treatments. For example, "peer support services" delivered by qualified individuals may be effective in facilitating recovery and assist in navigating health care resources as part of pain management treatment.

In Medicare Part D, coverage and tier placement of Part D drugs on the formularies of Part D plans, as well as use of utilization management, is subject to negotiations between the Part D plan sponsor, pharmacy benefit manager and drug manufacturer. CMS is statutorily prohibited from interfering in those negotiations. While plan sponsors are permitted to use utilization management techniques, such as prior authorization, as part of their formulary design, CMS annually reviews plan formularies to ensure the formulary complies with CMS' regulations. CMS does not approve a plan's bid if CMS finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program

are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Part D plan formularies are also required to include adequate representation of all necessary Part D drug categories or classes for the Medicare population.

4. **While I appreciate recent efforts by the Administration to address unique challenges facing rural hospitals, as you know, the closure rates for these vital sources of care are increasing at a concerning rate. CMS and other agencies within the U.S. Department of Health and Human Services have sought out various ways to help support the health services needs of rural communities, but more needs to be done. Each year, CMS recalibrates Medicare Severity-Diagnosis Related Group (MS-DRG) weights. Each year, CMS also includes the estimated impact of these changes in MS-DRG weights in the notice of the proposed update to the Inpatient Prospective Payment System (IPPS). Rural hospitals generally, and hospitals designated as Rural Referral Centers (RRCs), Sole Community Hospitals (SCHs) and Medicare-dependent Hospitals (MDHs) in particular, can be distinctly and disproportionately negatively impacted by these recalibrations. What steps is CMS taking to examine this phenomenon and consider making an adjustment, if deemed appropriate? If no steps are being taken, why not?**

CMS Response: In general, Medicare pays for hospital inpatient stays by using the Inpatient Prospective Payment System (IPPS) to pay a pre-determined, specific rate for each hospital discharge. CMS categorizes each discharge into one of over 700 Medicare Severity Diagnosis-Related Groups (MS-DRGs), and determines a "relative weight" for each MS-DRG that adjusts payments based on the average resources to care for cases in that MS-DRG as compared to the average resources to care for cases in all MS-DRGs. For example, the relative weight for MS-DRG 002 (heart transplant) is higher than the relative weight for MS-DRG 122 (acute eye infection), and Medicare will pay a higher amount for beneficiary discharges assigned to this MS-DRG.

Under statute, CMS is required to adjust the MS-DRG classifications and relative weights at least annually.[17] These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. CMS makes these changes as part of its annual IPPS rulemaking. We take the comments we receive as part of this rulemaking—along with other provider feedback we receive—very seriously to inform our decision-making as we work to pay hospitals an appropriate amount.

We anticipate that changes to the MS-DRGs and relative weights finalized in our FY 2020 IPPS Final Rule will result in an overall 0.0 percent change in payments for hospitals.[18] As discussed in the FY 2021 IPPS Proposed Rule, proposed changes due to the MS–DRGs and relative

[17] Section 1886(d)(4)(C) of the Social Security Act
[18] Final Rule available at: https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

weights would result in a 0.0 percent change in payments for hospitals.[19] Hospitals that generally treat cases in higher severity MS-DRGs will experience a slight increase in their payments, while hospitals that generally treat fewer of these cases will experience a decrease in their payments under the relative weights. We recognize the critical services provided by rural hospitals, including Rural Referral Centers, Sole Community Hospitals, and Medicare-dependent Hospitals. The Trump Administration has placed an unprecedented priority on improving the health of Americans living in rural areas, and last year, CMS furthered this commitment by introducing the agency's first Rural Health Strategy.[20] We will continue to monitor the impact our policies have on providers in rural areas, and we look forward to continuing our work with Congress, providers, and other stakeholders to improve our programs.

5. The Committee held a hearing in March 2018 examining HHS's efforts to respond to the seasonal influenza. At that hearing, FDA testified that CMS and FDA were working together to analyze Medicare data to compare Medicare patients that received cell-based vaccines to those who received egg-based vaccines to determine which vaccine was more effective in that population. Similarly, the Centers for Disease Control and Prevention (CDC) testified that CMS and FDA were collaborating to examine the best way to protect seniors from getting the flu.

a. What is the current status of this work?
b. How will CMS and FDA share their findings with stakeholders?
c. How will CMS use the information? How, if at all, should this information be used to shape reimbursement policy for the seasonal influenza vaccine?

CMS Response: CMS plays a limited but important role in this Administration's efforts to develop appropriate and effective medical countermeasures to seasonal influenza. Primarily, we support the work of our colleagues throughout the federal government, including the Food and Drug Administration (FDA), to study vaccines and conduct other research by allowing them access to valuable CMS data. For example, to support FDA scientists working to understand whether one type of influenza vaccine performs better than another in individuals 65 years of age or older, we provided data that allow the FDA to compare outcomes of Medicare patients that received cell-based vaccines to those who received an egg-based vaccine. We look forward to continuing our support of efforts across the federal government to protect seniors from influenza by providing secure, timely access to our databases when appropriate.

6. The Quality Innovation Network-Quality Improvement Organization (QIN-QIO) helps providers improve the quality of care delivered to Medicare beneficiaries. The QIN-QIO program fully lapsed in October

[19] Proposed Rule available at: https://www.federalregister.gov/documents/2020/05/29/2020-10122/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[20] CMS Rural Health Strategy available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf

a. **Why did CMS let the program lapse?**
b. **How long does CMS expect the lapse to continue?**
c. **What is CMS' view of the QIN-QIO program?**

CMS Response: On November 8, 2019, CMS awarded contracts to 12 experienced, community-based organizations to serve as the next wave of Quality Innovation Network-Quality Improvement Organization contractors under the Quality Improvement Organization 12th Statement of Work for a five-year period of performance. During this period, these contractors will provide targeted quality improvement assistance in many areas, including poor-performing nursing homes, small and rural communities, and communities serving vulnerable populations. This work builds on CMS's focus on patient outcomes, and CMS remains committed to pursuing continuous quality improvement within a variety of settings that advances the overall safety and quality of care provided to all beneficiaries.

7. **In June 2019, the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) released two reports regarding the potential abuse and neglect of Medicare beneficiaries. One of these reports, entitled "CMS Could Use Medicare Data to Identify Instances of Potential Abuse or Neglect," examines whether CMS could improve how the agency uses Medicare data to identify instances of potential abuse or neglect, and HHS OIG recommends that CMS use Medicare claims data to identify instances of potential abuse or neglect.**

   CMS disagreed with HHS OIG's recommendations to use claims data to identify instances of potential abuse or neglect, noting that claims data may not be timely enough to address acute problems in identifying and addressing potential abuse or neglect of Medicare beneficiaries.

   a. **According to HHS OIG, CMS did acknowledge that claims data could provide helpful insight into past incidents involving potential abuse and neglect. Is CMS exploring ways to use claims data to identify instances of abuse and neglect in nursing homes?**
   b. **Given that the Medicare administrative contractor received more than 75 percent of all the claims in HHS OIG's sampling frame in 30 days or fewer from the dates of service, why does CMS believe that it "may not be timely" to use claims data to identify instances of abuse and neglect?**
   c. **If CMS does not want to use claims data as HHS OIG recommends, what is CMS doing to improve how the agency identifies potential instances of abuse and neglect at nursing homes?**

CMS Response: Patient safety is CMS's top priority in all facilities that participate in the Medicare and Medicaid programs. CMS never tolerates abuse, neglect, or exploitation, and the Agency takes any allegation of these incidents very seriously. We are continuously looking for

ways to improve our approach to safety and quality and ensuring incidents of abuse and neglect are reported.

Monitoring patient safety and quality of care in facilities serving Medicare beneficiaries is an essential part of CMS's oversight efforts and requires coordinated efforts between the federal government and the states. To address the time-sensitive nature of abuse and neglect issues, CMS has a complaint intake and investigation process. CMS has agreements with state survey agencies to survey participating providers and suppliers and certify whether each entity complies with federal participation requirements. The state survey agencies not only inspect providers for compliance with Medicare health and safety standards, but also manage the intake of complaints and facility reported incidents and conduct investigations accordingly. State agencies, including law enforcement and adult protective services, play an integral role in investigating complaints of abuse and neglect in a variety of health care settings and are responsible for reporting substantiated findings to local law enforcement, and if appropriate, to the Medicaid Fraud Control Units.

While OIG's review of claims data provides helpful insight into past incidents involving potential abuse and neglect, including injuries of unknown source, this data may not be timely enough to address acute problems since providers generally have up to 12 months (one calendar year) from the date the service was provided to submit claims for services rendered. Additionally, OIG's methodology only applies to individuals enrolled in traditional Fee-For-Service Medicare, and does not include individuals enrolled in managed care, such as Medicare Advantage. Lastly, OIG envisions a system to analyze and identify potential cases for investigation, and route these cases into the appropriate state agency's tracking system. This would require a robust infrastructure of technology and staff. At this time, we are focusing our resources on our survey and certification activities, including complaint investigations.

CMS will continue to take strong enforcement actions when facilities violate federal regulations, and fail to prevent or report abuse. When CMS learns that a nursing home failed to report or investigate incidents of potential abuse and neglect, CMS will take immediate action against the nursing home. In addition to imposing civil monetary penalties against noncompliant facilities, CMS can, and under certain circumstances must, deny payments to or terminate a facility's Medicare and Medicaid participation agreements, when appropriate.

Additionally, CMS made an important enhancement related to transparency and equipping beneficiaries with new tools to choose high-quality nursing homes. Specifically, on October 23, 2019, CMS added an icon on Nursing Home Compare to identify nursing homes that have been cited for incidents related to abuse or neglect. This new tool is unprecedented, representing a major step forward in transparency for residents and families who are researching nursing homes on Nursing Home Compare. Text accompanying the icon encourages them to ask questions about a nursing home's policies with respect to abuse, enabling them to make the best choice for them.

CMS will be releasing additional guidance to surveyors to assure that facilities are appropriately identifying and reporting incidents of suspected abuse. CMS plans to strengthen the policies for state survey agencies to investigate facility-reported incidents of potential abuse, and if necessary, initiate referrals to law enforcement. Also, CMS is exploring options for improving the completeness and usability of data entered into our automated complaint tracking system and survey reports. These options range from basic platform upgrades, to implementing cutting edge technology, such as piloting the use of natural language processing to analyze the narrative text found within survey reports. We believe these and other actions will continue to improve our oversight of nursing homes and help prevent residents from abuse.

In addition, CMS announced new, enhanced oversight of state survey agencies.[21] The CMS Regional Offices conduct formal assessments annually of each state survey agency's performance relative to measures included in the State Performance Standards System. By upgrading the State Performance Standards System, CMS will be able to more quickly and rigorously analyze state agency performance. The upgraded system will allow CMS to more quickly identify state-specific concerns and target assistance and resources accordingly. The system will also provide state agencies with better access to CMS data to help them avoid redundant and unnecessary reporting, helping them conserve scarce resources.

CMS remains diligent in our duties to monitor facilities participating in Medicare and Medicaid across the country, as well as the state agencies that survey them, and we appreciate the ongoing work of the OIG in this area and will continue to work with them as we make improvements to our oversight efforts.

8. On October 17, 2019, CMS announced that CMS plans to more rigorously measure state survey agency performance to ensure the inspections that they conduct of nursing homes on behalf of CMS are timely and accurate. CMS also stated that it plans to ensure that enforcement actions—like civil money penalties—are applied consistently

a. At a hearing that the Oversight and Investigations Subcommittee held in September 2018, CMS testified that the agency was undertaking several actions to address concerns with oversight of state survey agencies. Among other things, CMS said the agency had started giving monthly feedback reports to state survey agencies to help them understand where their own deficiencies are, where there may be patters of inconsistencies, or where they are not appropriately citing deficiencies as they should. Is CMS still sending those monthly feedback reports to state survey agencies?

i. If so, what has been the experience with these monthly feedback reports thus far?

ii. If not, why not?

[21] https://www.cms.gov/newsroom/press-releases/trump-administration-unveils-enhanced-enforcement-actions-based-nursing-home-covid-19-data-and

b. During the hearing, CMS testified that the agency was overhauling the State Performance Standards System and that the effort may take at least a year to complete. Is this work completed or is the work still ongoing?

CMS Response: Resident safety is CMS's top priority in nursing homes and all facilities that participate in the Medicare and Medicaid programs. CMS works in partnership with state survey agencies to oversee nursing homes, since these agencies are generally also responsible for state licensure. The state survey agencies visit and survey every Medicare and Medicaid participating nursing home in the nation at least annually to ensure they are meeting CMS's health and safety requirements as well as state licensure requirements.

Making sure state survey agencies have the information they need to make improvements is a critical part of our efforts to improve our oversight of nursing homes. Each CMS Regional Office meets quarterly with state survey agencies in their regions to discuss issues, trends, and concerns. CMS distributes monthly performance feedback reports to the CMS Regional Offices and state survey agencies regarding the new computer-based, standard survey process (e.g., consistency with federal process, areas missed, and patterns).

In October 2019, we announced that as part of continuing efforts to keep nursing home residents safe and to respond to concerns about inconsistent and untimely inspections, CMS strengthened the system we use to hold inspectors accountable, the State Performance Standards System (SPSS). Under the changes, CMS will more rigorously and rapidly analyze state survey agency performance to ensure inspections are timely and accurate.[22] This includes new performance measures and stricter monitoring to ensure inspections are done in a fair, accurate, and timely manner, ensuring patient safety, and ensuring that enforcement actions—like civil money penalties—are applied consistently. CMS has also released the Fiscal Year 2018 SPSS results in a memo to states, which includes three years of performance evaluations based on 18 measures from Fiscal Years 2016 to 2017.[23] CMS is always looking for ways to improve our quality and safety oversight efforts to safeguard nursing home residents, and we expect state survey agencies to use the information we provide to enhance their efforts and hold nursing homes accountable for providing safe, high-quality care.

9. In September 2016, the Senate Committee on Finance and this Committee wrote to HHS OIG expressing serious concerns with CMS' oversight of the Medicaid Drug Rebate program to ensure the correct classification of the EpiPen. In response to these letters, HHS OIG has released three reports examining various aspects of CMS' oversight of the Medicaid Drug Rebate program.

[22] Memo to states available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/AdminInfo-20-02-ALL.pdf
[23] Memo to states available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/AdminInfo-20-01-ALL.pdf

In HHS OIG's most recent report entitled "Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices," HHS OIG found that the use of reasonable assumptions is common practice among responding manufacturers, and that nearly two-thirds of the manufacturers wanted additional guidance from CMS on assumptions-related issues.

a. **Why has CMS historically provided little formalized oversight of the reasonable assumptions process?**
b. **HHS OIG recommended that CMS could take additional steps to improve oversight in this area. What does CMS plan to do to improve oversight of the assumptions that manufacturers make when they calculate the average manufacturer prices (AMPs) and best prices (BPs)?**

CMS Response: CMS is committed to ensuring the integrity of the Medicaid Drug Rebate Program so that prescription drugs are affordable for states and accessible for Medicaid beneficiaries. The Medicaid Drug Rebate Program is a partnership between CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The program requires a drug manufacturer to enter into, and have in effect, a National Drug Rebate Agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are required to report all of their covered outpatient drugs to the Medicaid Drug Rebate Program. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government.

The rebate amount owed for each drug is based on the average manufacturer price (AMP), and in certain circumstances, the best price (BP) reported by manufacturers. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculation of AMP and BP, consistent with the general requirements and intent of section 1927 of the Social Security Act, Federal regulations and the National Drug Rebate Agreement. In accordance with the requirements of the National Drug Rebate Agreement, each manufacturer must maintain adequate documentation supporting its assumptions. CMS guidance also states that manufacturers are not required to submit their assumptions and their receipt is not considered acquiescence by CMS.[24] However, CMS has the ability to request manufacturers' records of reasonable assumptions for purposes including formal oversight inquiries, manufacturer recalculations, and technical assistance.

CMS also communicates regularly with manufacturers and provides technical assistance related to assumptions used in calculations. In addition, to increase transparency and efficiency, CMS also publishes guidance when we identify common issues or questions manufacturers may have

[24] Manufacturer Release No. 78

regarding a specific Medicaid drug rebate topic, and ensures that the entire sector has access to this information.[25] For example, on June 5, 2020, CMS issued Manufacturer Release #113, which provides guidance for how CMS will be implementing the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116-16) and explains how drug manufacturers can ensure they are complying with the drug pricing and drug product information reporting requirements in Section 1927 of the Act. Specifically, this guidance explains the new enforcement authority provided to the Secretary, including civil monetary penalties, under the Medicaid Services Investment and Accountability Act of 2019 to ensure drug manufacturers report the correct drug category and other drug product information and to impose penalties against manufacturers that knowingly misclassify or otherwise misreport their drug products. The guidance also explains that if a manufacturer fails to correct the misclassification of a drug in a timely manner, the Secretary can take any or all of the following actions: (1) Correct the misclassification on behalf of the manufacturer; (2) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's rebate agreement, and exclude the misclassified drug from Federal financial participation (FFP) (correlating amendments to section 1903 of the Act); and (3) Impose civil monetary penalties for each rebate period during which the drug is misclassified subject to certain limitations. More information on Manufacturer Release #113 may be found here: https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf

We greatly appreciate the work and recommendations of the Department of Health and Human Services Office of Inspector General (HHS-OIG). We will continue to work with HHS-OIG as we work to implement its important recommendations across our programs.

10. Stakeholders are concerned that the agency's Radiation Oncology Model is much more focused on achieving a particular savings target and less so on creating a better payment model that promotes patient access to innovative cancer therapies.

- **a. Why has CMS historically provided little formalized oversight of the reasonable assumptions process?**
- **b. Other CMMI models allowed for voluntary participation so that only providers who were ready to take on risk had payment changes. The RO model from CMMI would only give a few months' notice to providers that their payments are going to change dramatically by mandate. Why is CMMI proposing such little notice time for providers to prepare?**
- **c. This CMMI model seems to have the largest risk proposed by CMMI compared to all previous models. For example, it starts immediately, and the proposed cuts are much bigger than other models – such as a Professional and Technical Fee cut with the 5 percent bonus only allocated to the professional not technical fees. Why is CMMI proposing that RO be treated differently with the size and timing of the payment change?**

[25] https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html

d. The RO model proposes to change payments for 40 percent of episodes, one of the largest proportions ever proposed by CMMI. Why did CMMI decide on 40 percent of episodes? Why not start the first few years with the model being a demo and only applying to 10 percent of episodes?

e. Under the RO Alternative Payment Model, providers could face a cut that could affect their ability to provide care to patients. There are concerns that the model includes too large of a discount rate that will lead to inadequate reimbursement for providers of radiation therapy services. Has CMS considered reducing the size of the proposed discount rate or examined potential impacts to reimbursement and patient access?

CMS Response: CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs, including among beneficiaries with cancer. We have undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model. We believe that a model in radiation oncology would further these efforts to test ways to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures. In July 2019, CMS issued a notice of proposed rulemaking that would establish a Radiation Oncology (RO) Model. This proposal is a way to solicit feedback from stakeholders, including stakeholders who will implement the RO Model, so that we can ensure that our policy efforts are guided by the real experience of clinicians on the frontlines.

As we noted on the RO Model website[26], the notice of proposed rulemaking proposed that the RO Model would begin on January 1, 2020. As this date has already passed and we have not yet issued a final rule, the RO Model, if finalized, would not begin on this date. If finalized, we would provide information on the effective date of the RO Model in the final rule.

Radiotherapy is a common treatment for nearly two thirds of all patients undergoing cancer treatment[27, 28] and is typically furnished by a radiation oncologist at either a hospital outpatient department or a freestanding radiation therapy center. The RO Model would test whether prospective episode-based payments to physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiotherapy episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Under our proposal, the RO Model would require the participation of providers and suppliers that might not otherwise participate in these models, and would be tested in multiple geographic areas, and would include 40 percent of radiation oncology episodes in eligible geographic areas.

Through discussions with radiotherapy (RT) experts, evaluation experts and actuaries, we determined that a mandatory model would be the best approach to test the proposed episodic payments effectively. Requiring participation in the RO Model would ensure sufficient

[26] The RO Model website can be accessed at: https://innovation.cms.gov/initiatives/radiation-oncology-model/.
[27] Physician Characteristics and Distribution in the U.S., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.
[28] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

proportional participation of both hospital outpatient departments and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers or RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model. Testing the Model in this manner would also allow us to learn more about patterns of utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy.

CMS designed the proposed RO Model to qualify as both an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM under the Quality Payment Program. Under the Quality Payment Program, qualifying eligible clinicians who participate in Advanced APMs receive a 5 percent lump sum APM Incentive Payment. We estimate that 82 percent of participating clinicians would receive the Advanced APM Incentive Payment under the proposed RO Model at some point during the model performance period, and those who do not qualify could be eligible for MIPS under the APM scoring standard.

Currently, Medicare uses two different payment systems to pay for radiotherapy services provided in hospital outpatient departments and for the same radiotherapy services provided in free-standing radiation therapy centers. Because of differences in these two payment systems, without the waiver included in our RO Model proposal, clinicians furnishing services in freestanding radiation therapy centers would have their APM Incentive Payment calculated based on both professional and technical episode payments, while clinicians furnishing services in hospital outpatient departments would have their APM Incentive Payment calculated based only on the professional episode payment. We believe this potential difference between how technical episode payments are treated would create potentially misaligned incentives among RO Model participants. Specifically, we believe that there could be an incentive for participants to shift the setting in which they furnish radiotherapy services from hospital outpatient departments to freestanding radiation therapy centers in order to increase the amount of technical component payments that they receive, resulting in unwarranted increases in their APM Incentive Payment amount. We believe this would prejudice the model testing of site neutral payments.

We explained in the proposed rule that we had determined that 40 percent of eligible episodes in eligible Core Based Statistical Areas nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test, and that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model. RO Model participants treating beneficiaries with one of 17 included cancer types would receive prospective, episode-based payment amounts for radiotherapy services furnished during a 90-day episode of care, instead of regular Medicare Fee-for-Service payments. Participant-specific payment amounts would be determined based on proposed national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. CMS would further adjust payment amounts by applying a discount factor. The discount factor, or the set percentage by which CMS reduces an episode payment amount, would reserve savings for Medicare and reduce beneficiary cost-sharing.

The goal for this Model is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for RO Model participants. We believe the proposed Model would further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer.

11. The CDC describes antimicrobial resistance as "one of the biggest public health challenges of our time. Each year in the U.S., at least 2 million people get an antibiotic-resistant infection, and at least 23,000 people die." How is CMS working with HHS and other federal partners to address the challenges that antimicrobial resistance presents?

- **a. How is CMS working with HHS and other federal partners to utilize and promote public-private partnerships to address antimicrobial resistance?**
- **b. Have these partnerships been impacted by the diminishing number of companies working to develop new products to address pathogens that have become resistant to existing drugs?**

12. Some small companies that have created FDA-approved products to combat antimicrobial resistance have filed for bankruptcy or are abandoning their research and development efforts in an attempt to survive in an unsustainable commercial marketplace. What can Congress, CMS, HHS, and other federal partners do to foster and incentivize coordinated action between the government, industry, regulators, prescribers, and payers?

13. It is my understanding that the agency has indicated its desire to review larger diagnosis-related group (DRG) changes to help support antibiotic development. Why is DRG reform important to the future of antibiotic development?

14. In addition to CMS' new inpatient rule that aims to remove reimbursement barriers to the appropriate use of new antimicrobials, what more can CMS do to improve the Medicare inpatient system to ensure patient access to optimal antimicrobials?

CMS Response to 11-14: Antimicrobial resistance is an ongoing public health crisis, and this Administration is leading the way to improve incentives for innovation. CMS recognizes antibiotic developers face difficulties in receiving sufficient payment to reflect the value of these medical products. Because the Inpatient Prospective Payment System makes a single payment for all the services for a given diagnosis under a diagnosis-related group (DRG), hospitals may be incentivized to prescribe cheaper antibiotics, which are usually generic drugs that were not designed to address drug-resistant infections. As part of its final policies to foster innovation more broadly for drugs and devices, CMS has taken specific policy steps to reform antibiotic payment. Congress created the new technology add-on payment (NTAP) in 2000 as a time-

limited enhanced payment for new drugs or devices. The intent of the program was to smooth market entry for new innovations while providing time for the relevant DRG to recalibrate to accommodate payment for new products.

In the FY 2020 IPPS final rule, CMS finalized a number of changes to foster antibiotic innovation and secure beneficiaries' access to these medications.[29] For example, we finalized a NTAP pathway for eligible antimicrobial products that does not require these products to meet the "substantial clinical improvement" criterion. CMS also increased the add-on payment percentage from 50 to 75 percent for Qualified Infectious Disease Products (QIDPs) - a designation that the FDA can grant to incentivize the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. In addition, targeting payment reforms to QIDPs has the added benefit of providing developers with some additional market predictability, as innovators can receive QIDP status very early in the commercialization process and far in advance of CMS coverage determinations. Collectively, these policy changes will reduce barriers to antibiotics innovation while increasing predictability and payment for novel drugs.

CMS also changed Medicare billing codes to better reflect the increased costs hospitals experience when treating an inpatient who develops antimicrobial resistance. By increasing payments to hospitals treating beneficiaries with antimicrobial resistance, our policy will create the financial flexibility for physicians to prescribe the appropriate new antibiotics without imposing an additional fiscal burden upon hospitals.

Specifically, to reflect the additional resources needed to care for patients with antimicrobial resistance, CMS changed the severity level designation for multiple ICD-10 codes for antimicrobial resistance from a non-CC designation to a "CC" designation. This "CC" designation indicates the presence of a complication or comorbidity in a given inpatient case that requires the hospital to dedicate more resources for the care of that patient than typically needed for the specific diagnosis. While the code changes above represent a starting point, we recognize that drug-resistant infections may arise across many diagnostic indications. Consequently, we will continue to explore whether additional reforms are needed to recalibrate DRGs to better account for the clinical complexity of drug resistance.

CMS is committed to ensuring that its policies support the pipeline of drug development and enable Medicare beneficiaries and all Americans to access life-saving medicines. The of incentives for innovation in the final FY 2020 Inpatient Prospective Payment System Rule should pave the way from bench to bedside for new antibiotics, while the agency's revision of antibiotic stewardship rules and consideration of DRG redesign should lay the groundwork for future policy action.

[29] Available here: https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-16762.pdf

15. A new Medicare Condition of Participation requires hospitals to implement antibiotic stewardship programs to guide optimal antibiotic use. Evidence suggests that stewardship programs improve cure rates, reduce antibiotic resistance, and lower health care costs. How will CMS work with hospitals to implement stewardship and to report data on antibiotic use and resistance?

a. Has CMS considered stewardship in outpatient settings?

CMS Response: CMS is committed to addressing payment reform with regard to antimicrobial resistance and to investing in public health infrastructure like stewardship programs to slow the development of resistance to existing drugs. In September 2019, CMS issued a final rule that included requirements for the implementation of antibiotic stewardship programs as part of the Conditions of Participation for hospitals and critical access hospitals in the Medicare and Medicaid programs (84 Fed. Reg. 51732, September 30, 2019). We believe that the new requirements for antibiotic stewardship programs will provide a critical tool for hospitals and critical access hospitals to use in the fight against the emergence of new strains of antibiotic-resistant bacteria and in the defense of our currently effective antimicrobials. CMS will continue to explore opportunities to encourage proper antibiotic stewardship across care settings, including outpatient settings.

16. During the hearing, I asked you a question about the hospital star rating methodology and CMS' announcement in August 2019 on the upcoming enhancement of overall hospital quality star ratings. Can you please provide a timeline of when the ratings on CMS' website will be updated?

CMS Response: CMS plans to update the quality measurement methodology of the Overall Hospital Quality Star Ratings located on our Hospital Compare website in 2021. In the interim, CMS will next refresh the Star Ratings using the current methodology in early 2020, ensuring patients have timely access to the most up-to-date hospital quality information while a new methodology is being finalized. CMS posted a summary of the more than 800 comments received on potential technical changes to the Hospital Compare Overall Star Ratings during a public comment period that ended March 29, 2019. An additional public listening session was held on September 19, 2019. This public feedback we have received is a critical part of ongoing efforts, along with comments we anticipate receiving during future rulemaking that will help shape improvements to the Star Ratings targeted for early 2021.

The Honorable Michael C. Burgess (R-TX)

1. The Medicare Access and CHIP Reauthorization Act was a critical piece of legislation that was signed into law in 2015. It repealed the sustainable growth rate and began shifting Medicare payments away from volume and towards value. The proposed radiation oncology model is proposed as an Advanced Alternative Payment Model, but

CMS is proposing to waive MACRA's five percent advanced APM bonus for the technical component of freestanding payments. However, the model would still apply a five percent cut on the technical payments for those same centers. Should CMMI be prioritizing the evaluation of a program over MACRA requirements and fairness to participants?

2. **The proposed radiation oncology model is mandatory and would require about 40 percent of radiation oncology practices to participate at the outset and has a quicker transition and more risk required at the outset than the Comprehensive Joint Replacement and Oncology Care Models. Why do you believe the Radiation Oncology model should be mandatory prior to volunteer testing? Do you believe it is fair for those outside of the model that would like to participate to be restricted from doing so for a minimum of five years?**

CMS Response to 1 and 2: CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs, including among beneficiaries with cancer. We have undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model. We believe that a model in radiation oncology would further these efforts to test ways to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures. In July 2019, CMS issued a notice of proposed rulemaking that would establish a Radiation Oncology (RO) Model. This proposal is a way to solicit feedback from stakeholders, including stakeholders who will implement the RO Model, so that we can ensure that our policy efforts are guided by the real experience of clinicians on the frontlines.

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multiple geographic areas, and would include 40 percent of radiation oncology episodes in eligible geographic areas.

Through discussions with radiotherapy (RT) experts, evaluation experts and actuaries, we determined that a mandatory model would be the best approach to test the proposed episodic payments effectively. Requiring participation in the RO Model would ensure sufficient proportional participation of both hospital outpatient departments and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers or RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model. Testing the Model in this manner would also allow us to learn more about patterns of utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy.

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We explained in the proposed rule that we had determined that 40 percent of eligible episodes in eligible Core Based Statistical Areas nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test, and that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model. RO Model participants treating beneficiaries with one of 17 included cancer types would receive prospective, episode-based payment amounts for radiotherapy services furnished during a 90-day episode of care, instead of regular Medicare Fee-

for-Service payments. Participant-specific payment amounts would be determined based on proposed national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. CMS would further adjust payment amounts by applying a discount factor. The discount factor, or the set percentage by which CMS reduces an episode payment amount, would reserve savings for Medicare and reduce beneficiary cost-sharing.

The goal for this Model is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for RO Model participants. We believe the proposed Model would further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer.

3. **As and OB/GYN, I am incredibly concerned about the maternal mortality rates across the United States. As Dr. David Nelson recently testified at a Health Subcommittee hearing about maternal mortality, it is clear that there are ways to successfully limit maternal morbidity and mortality within the Medicaid population, but not without great effort. How is CMS working with states to empower them with the flexibility and the resources they need to address maternal health and mortality in their Medicaid populations?**

   Follow-up: Are there any tools that CMS does not currently have that would be helpful addressing maternal mortality?

CMS Response: As the single largest payer for maternity care in the United States, Medicaid plays an important role in perinatal and maternal health. In 2014, CMS launched its Maternal and Infant Health Initiative (MIHI) to explore program and policy opportunities to improve outcomes and reduce the cost of care for women and infants in Medicaid and CHIP. Since then, much work has been done, such as the Postpartum Care Action Learning Series, a learning collaborative of states to drive quality improvement around postpartum care, and a three-year pilot in four States to test whether direct outreach to expectant mothers enrolled in Medicaid through mobile messaging could improve care.

CMS is currently evaluating activities over the past five years, which includes publishing three Issue Briefs on March 9, 2020, to describe initiatives undertaken in the first phase of MIHI. These Issue Briefs are:

- Lessons Learned About Payment Strategies to Improve Postpartum Care in Medicaid and CHIP: This brief outlines the lessons learned about payment strategies to improve postpartum care visit rates and summarizes the changes three states made related to

paying for maternity care in order to improve postpartum care under the Postpartum Care Action Learning Series.[33]

- The Maternal and Infant Health Initiative Grant to Support Development and Testing of Medicaid Contraceptive Care Measures: The CMS MIHI grant program supported development and testing of Medicaid contraceptive care measures. This analytic brief discusses the MIHI grant program, describes the contraceptive care measures developed as part of this effort, summarizes data reported by the MIHI grantees, highlights uses of the data, and identifies lessons learned.[34]
- Improving Postpartum Care: State Projects Conducted through the Postpartum Care Action Learning Series and Adult Medicaid Quality Grant Program: This issue brief describes the quality improvement teams in the 10 states, their aims, the interventions they tested, their results, and lessons learned. In addition, this fact sheet provides summaries of the postpartum care-related projects that four states undertook as Adult Medicaid Quality grantees.[35]

Additionally, CMS is reconvening an expert workgroup to help chart a course for the future of maternal infant health quality measurement and improvement. The workgroup will represent a wide variety of key stakeholders and federal agencies and will provide updated recommendations for measurement, quality improvement and technical assistance opportunities.

In Medicaid and CHIP, the measures in the voluntary Child and Adult Core Sets assess the quality of care women receive at each step in their lifecycle and include quality measures associated with major drivers of pregnancy-related mortality and severe maternal morbidity. CMS has identified a subset of 11 Child and Adult Core Set measures that comprise a Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set).[36] The Maternity Core Set includes a measure of early elective delivery, along with measures that examine prenatal and postpartum care, low birth weight babies and well-baby care. Since the core sets were established in 2010 and 2012, states have made significant progress reporting these measures. With the passing of the Bipartisan Budget Act of 2018 (P.L. 115-123), state reporting of the Child Core Set, including maternal and infant health measures, will become mandatory beginning in 2024.

The Medicaid and CHIP Scorecard is a central component of CMS's commitment to increase public transparency and accountability about the programs' administration and outcomes.[37] The Scorecard currently includes one maternal health measure (Postpartum Care). Over time, the Scorecard will evolve to include health outcome metrics, and we are considering how the Scorecard can address maternal and infant health. CMS continues to work with states to encourage greater reporting to improve consistency across states.

[33] Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-payment-strategies.pdf
[34] Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/mihi-contraceptive-measures.pdf
[35] Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/postpartum-als-state-projects.pdf
[36] Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2020-maternity-core-set.pdf
[37] Available at: https://www.medicaid.gov/state-overviews/scorecard/index.html

In addition, through the Innovation Center, CMS is committed to testing models designed to improve outcomes in maternal and infant health care. The Innovation Center's Strong Start for Mothers and Newborns Initiative tested three different maternity care models that aimed to reduce preterm birth, improve overall pregnancy outcomes for mothers and infants, and reduce costs during pregnancy and for the year following birth. This model, which was tested from 2013-2017, showed significant improvements in outcomes among mothers who received care in birth centers that followed the midwifery model of care. CMS issued a joint informational bulletin on November 9, 2018, that discusses the model's evaluation results and reviews options to cover midwifery services under Medicaid programs.[38]

Additionally, CMS is also working to incorporate maternal health-related measures into its quality programs for hospitals and clinicians. In the Hospital Inpatient Quality Reporting (IQR) Program, for example, there is an early elective delivery quality measure in the program, and CMS is considering additional measures for future incorporation.

4. Medicare is poised to cut rates for home health providers beginning in January 2020. How is CMS planning to monitor and mitigate any problematic or unintended consequences of those cuts?

CMS Response: In October 2019, CMS finalized updates to the home health payment rates for calendar year (CY) 2020, including setting forth the implementation of the Patient-Driven Groupings Model (PDGM) as required by the Bipartisan Budget Act of 2018, which also set the home health payment update for 2020 at 1.5 percent. The PDGM is a new case-mix payment methodology for home health services, which more accurately pays for home health services and focuses on patient needs by relying heavily on patient characteristics rather than volume of care. As required by the Bipartisan Budget Act of 2018, the PDGM will be implemented in a budget neutral manner and is expected to result in an overall net zero-dollar impact. While some home health agencies will experience lower payments, others—such as rural and nonprofit home health agencies—will likely see an increase in payments.

As we do with any major policy change, CMS will continuously monitor the impact the change has on beneficiaries, providers, and other stakeholders, and we will continue to gather feedback to inform us as we examine ways to improve our programs. We also provide helpful tools and resources for providers as they work to meet our new requirements and estimate the impact our policies will have on their practice.

5. CMS published criteria for removing National Coverage Determinations that are outdated or clinically irrelevant for the Medicare population in the "Revised Process for Making National Coverage Determinations" notice in August 2013. CMS has used this process infrequently despite its stated intent to further simplify the administrative

[38] Available at: https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib110918.pdf

burdens of the Medicare program. Since 2013, CMS has only proposed 12 NCDs for removal and has only removed 8 NCDs through two deregulatory actions. CMS has not proposed any actions to remove NCDs since 2015. Why has CMS limited the utilization of this policy? What is CMS' timeline for reviewing and removing additional outdated NCDs?

CMS Response: CMS's annual Report to Congress[39] lists the NCDs implemented each year and notes which are reconsiderations. CMS prioritizes requests for NCD review based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

Since 2013, CMS has used an administrative procedure to periodically review the inventory of NCDs that are over ten years from their most recent review and evaluate the continued need for those policies to remain active on a national scale. Under the expedited process to remove NCDs announced in 2013,[40] CMS considered removing a total of twelve NCDs in 2013[41] and 2015.[42] In response to public comment, CMS ultimately removed eight of those NCDs.

While the expedited process is designed to capture NCDs that have not been reviewed in over ten years, an NCD might be reviewed more frequently for various reasons. For example, an NCD might be reviewed because of new scientific evidence and/or a reconsideration request from practitioners, patients, or other members of the public. NCD review may result in removal of the NCD, but it can also lead to expansion, contraction, or other alterations in the clinical characteristics for coverage and/or covered services.

The Honorable David B. McKinley (R-WV)

1. **According to the Centers for Disease Control and Prevention (CDC), 12.7 percent of adults in West Virginia were diabetic in 2016. Since 2013, Congress worked to ensure Medicare coverage of continuous glucose monitoring (CGM) devices; however, it took your leadership in 2018 to finally provide coverage for these devices with mobile device usage to hundreds of thousands of Medicare beneficiaries. As technologies for Medicare beneficiaries with diabetes continues to evolve in ways that do not fit cleanly into the existing Medicare construct, how will you continue to ensure that these innovative CGMs are available to seniors?**

CMS Response: The advent of novel medical technologies requires CMS to remove barriers to ensure safe and effective treatments are readily accessible to beneficiaries without delaying patient care. Our goal is to get new innovations to our beneficiaries concurrent with FDA

[39] https://www.cms.gov/files/document/2018-report-congress.pdf
[40] https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf
[41] https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=29
[42] https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=32

approval by removing government barriers to innovation and harmonizing CMS coverage, coding, and payment.

CMS announced[43] in 2018 that Medicare's coverage policy would support the use of continuous glucose monitors (CGMs) in conjunction with a smartphone, including the important data sharing function they provide for patients and their families. Prior to this change, CMS heard from numerous stakeholders who shared their concerns that Medicare's CGM coverage policy limited their use of CGMs, preventing them from sharing data with family members, physicians, and caregivers. After a thorough review of the law and our regulations, CMS decided that Medicare's published coverage policy for CGMs would be modified to support the use of CGMs in conjunction with a smartphone. In evaluating Medicare coverage of CGMs and other innovative glucose monitoring devices, we will take both stakeholder input as well as our own statutory obligations and relevant regulations into consideration.

2. What innovations for diabetes energize you to continue to push against the boundaries of an outdated Medicare system?

CMS Response: At CMS, our work is guided by 16 strategic initiatives, one of which is fostering innovation. Our vision is ambitious yet achievable: to protect and secure Medicare and ensure beneficiaries have access to the latest medical technologies and treatments. CMS is working to make sure that safe and effective treatments are readily accessible to beneficiaries by removing regulatory barriers. For example, under this Administration, CMS made policy changes to allow Medicare Part D plans to cover disposable insulin pumps. The President's FY 2020 Budget also includes a proposal to expand coverage of disposable devices, such as innovative glucose monitors and insulin pumps that substitute for a durable device, for use in the management and treatment of diabetes.

3. I appreciate this Administration's commitment to fighting the opioid crisis. However, I think more could be done, particularly as it relates to preventing opioid use disorder (OUD) before it takes hold. In 2017 this Committee passed landmark legislation – the SUPPORT for Patients and Communities Act – to give agencies such as CMS much needed tools to fight the opioid crisis. To your credit, CMS has moved forward in implementing many of the provisions of the law, but I feel one section of the bill in particular – Section 6082 – has been overlooked by CMS. Aimed at ensuring hospitals are able to offer proven non-opioid therapies to seniors rather than relying solely on prescription painkillers to manage seniors' pain, Section 6082 required CMS to review current payment policies for evidence-based non-opioid drugs and devices "with a goal of ensuring that there are not financial incentives to use opioids instead," and to revise payment where needed to remedy misaligned financial incentives. Access to alternatives that have demonstrated through published studies the ability to reduce

[43] https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center

opioid use while effectively managing pain is particularly critical. So, I was surprised to see that CMS claimed in its 2020 Outpatient Prospective Payment System (OPPS) proposed rule that no payment revisions were needed as CMS' analysis indicated there are no non-opioid therapies that have experienced decreased utilization in recent years. I think it's pretty clear these types of non-addictive alternatives have been underutilized in the past, which in turn has contributed to the opioid crisis. Continuing these misguided payment policies will only serve to exacerbate the crisis rather than address it. It was not this Committee's intent – nor is it consistent with the plain language of the statute – to limit payment adjustments under Section 6082 to therapies that have exhibited decreasing utilization over time.

Will CMS commit to revisiting implementation of Section 6082 through the 2020 OPPS final rule to ensure seniors are not discouraged from accessing proven non-opioid pain management alternatives?

4. **Why doesn't CMS provide separate reimbursement for non-opioid pain management approaches in the hospital outpatient setting?**

5. **In the CMS Roadmap for Fighting the Opioid Crisis, you state that a top priority of your agency is to "[m]anage pain using a safe and effective range of treatment options that rely less on prescription opioids." As you know, one of the reasons prescription opioids are so widely used is because they are a very inexpensive therapy. Do you think that we will truly be able to move away from opioids if we do not create a level playing field between opioids and other alternatives?**

    a. **Is CMS willing to explore options that prioritize, incentivize, and properly reimburse for alternatives?**

6. **I share the President's goal of wanting to reduce opioid prescribing by a third by 2021. I think this is a good goal, but we still have to treat the roughly 100 million Americans who have a surgical procedure every year and help them manage their pain. How can we appropriately treat these patients, while meeting the President's goal, without increasing the utilization of non-opioid pain management approaches?**

7. **As you know, the HHS-led Pain Management Best Practices Inter-Agency Task Force released its final report in May. Included in this report were numerous recommendations to prioritize utilization of non-opioid approaches, including by using them "as first-line therapy… in the inpatient and outpatient settings." In July, CMS released draft guidance dictating payment policy proposals for these patients which, unfortunately, did not include proposals to better incentivize these approaches. With this in mind, can you share how CMS is intending to implement this – and other – recommendations from the Task Force calling for incentivizing and prioritizing the utilization of non-opioid pain management approaches?**

8. **As you know, there are evidence-based approaches that have demonstrated the ability to help patients manage their acute pain symptoms. In 2019, CMS made a conscious decision to incentivize the utilization of these approaches for patients treated in an Ambulatory Surgical Center (ASC). Unfortunately, CMS made no such similar policy recommendation for patients treated in a hospital outpatient setting. In doing so, CMS has potentially denied millions of patients, including eight million Medicare beneficiaries who aren't ASC-eligible, access to non-opioid therapies to manage their pain. Can you explain the rationale for not providing ALL patients with access to these therapies?**

9. **Given the work that the Center for Medicare and Medicaid Innovation (CMMI) is doing to test models to curb the ongoing crisis, and the increased encouragement to utilize bundled-payment models in the recently proposed Physician's Fee Schedule, would the agency/CMMI consider implementing a demonstration model to test bundled-payment services for opioid detoxification in order to overcome access barriers with this option, so that patients can have a choice to select a version of medication-assisted treatment (MAT) that is most appropriate for them?**

10. **Given your knowledge for how best to implement successful Medicaid waiver programs for states' ability to use additional tools to help manage their unique populations, are there waivers being considered at CMS that enhance access to MAT in order to offer a treatment option to patients to help end this crisis?**

11. **Regarding the bundled payment proposals for OUD treatment medications, how will CMS know whether the fee schedules in the Final Rule are adequate for work that needs to be performed for the different medications? For example, we understand that some of the injectable opioid addiction treatment medications are relatively involved.**

12. **We understand that substance use disorder treatment physicians are among the most poorly compensated healthcare professions. If we want to end this opioid crisis, we need to pay the people doing the work appropriately. Has CMS incorporated adequate financial incentives into the fee schedules to adequately reimburse physicians for the work involved?**

CMS Response 3-12: As of September 2019, CMS fully implemented 11 sections of the SUPPORT Act. These include issuing Medicaid non-opioid pain guidance and issuing $50 million in grants to 15 states through a demonstration project to increase substance use provider capacity in the Medicaid program as required by section 1003 of the SUPPORT Act. Also, CMS has worked with state Medicaid programs to ensure they have the tools they need to address the opioid crisis. As an example, to date, CMS has approved 27 section 1115 demonstrations, which have permitted states to expand their full continuum of care for opioid use disorder and substance use disorder treatment.

13. The Protecting Access to Medicare Act of 2014 (PAMA) was intended as an opportunity to reframe Medicare's static payment system for laboratory diagnostic tests under the Clinical Laboratory Fee Schedule (CLFS) to a market-based system by linking Medicare payment rates to the rates paid by private payors in the commercial sector. As part of implementation of PAMA, CMS analyzed private-payer data it collected from about 2,000 laboratories to develop new payment rates for individual laboratory tests on the CLFS. CMS excluded data from nearly all hospital outreach laboratories and the overwhelming majority of physician office laboratories in setting new payment rates

- **a. What steps is CMS taking to collect private-payer data from all laboratories required to report under PAMA?**
- **b. How is CMS planning to ensure representative data collection efforts, particularly as it relates to hospital outreach laboratories and physician office laboratories?**
- **c. Is CMS working with relevant stakeholder to ensure a more transparent and clear process for data collection?**
  - **i. If yes, what specific actions has CMS done or will CMS do to increase transparency?**
  - **ii. If no, why not?**

CMS Response: Prior to implementing these new Medicare rates, CMS was required to collect certain private payer rate data from applicable laboratories to inform the rate setting process. Through notice and comment rulemaking (81 FR 41035), CMS considered stakeholder input in establishing parameters for the collection of the applicable information. In addition to rulemaking, CMS posted press releases and fact sheets on the CMS website describing the changes required by section 2 l 6(a) of PAMA and its progress in implementing the law. CMS held three national provider calls focused on data reporting and the data collection system. As a result of these efforts, the data reported to CMS during the initial data reporting period captured more than 96 percent of laboratory tests on the CLFS, representing over 96 percent of Medicare's spending on CLFS tests in calendar year 2016. Laboratories from every state, the District of Columbia, and Puerto Rico reported applicable information. To determine if CMS could improve the 96 percent reporting rate without creating significant further burden for laboratories, particularly small laboratories, CMS modeled three additional reporting scenarios to estimate the impact of increasing data reporting.[44] Based on this analysis, CMS determined that additional reporting requirements were not likely to result in a significant change to payment amounts, irrespective of how many additional laboratories reported. However, CMS noted that it would continue to analyze the effect of additional data when setting Medicare payment rates in the future.

[44] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf

In preparation for the data collection period for most tests that ran from January 1, 2019, through June 30, 2019, CMS made two changes to the definition of applicable laboratory in the Medicare Physician Fee Schedule Calendar Year 2019 final rule (83 FR 59671, 60033 and 60074), which CMS believes will lead to an even more robust data collection from which to calculate payment rates for the next CLFS update, as more laboratories may be required to report data. First, the final rule excludes Medicare Advantage plan payments from the total Medicare revenues, the denominator of the Medicare revenues threshold, which CMS believes will result in more types of laboratories qualifying as an applicable laboratory. CMS believes that its previous interpretation of total Medicare revenues, which included Medicare Advantage revenues, may have had the effect of excluding certain laboratories from meeting the majority of Medicare revenues threshold criterion and, therefore, from qualifying as applicable laboratories. In addition, CMS amended the definition to include hospital outreach laboratories that bill Medicare Part B using the CMS-1450 14x Type of Bill.

Regarding the data collected in 2019, as a result of Section 105 of the Further Consolidated Appropriations Act of 2020, CMS delayed the data reporting period for the 2019 data by one year (until 2021). CMS is continuing to evaluate ways to increase data reporting, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory.

14. Earlier this year, the Centers for Medicare and Medicaid Innovation (CMMI) released a proposed Radiation Oncology Alternative Payment Model (RO-APM). The proposal helps move to a bundled payment system for radiation therapy treatments for cancer patients in the Medicare program. While I support the concept of a model, I have specific concerns. For example, the demo includes 40 percent of radiation oncology episodes – far exceeding the size of what would be commonly understood as a demonstration. Will CMS consider reducing the size of a demonstration to a more appropriate size commensurate with a test, somewhere around 10 percent or less of radiation oncology episodes?

CMS Response: CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs, including among beneficiaries with cancer. We have undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model. We believe that a model in radiation oncology would further these efforts to test ways to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures. In July 2019, CMS issued a notice of proposed rulemaking that would establish a Radiation Oncology (RO) Model. This proposal is a way to solicit feedback from stakeholders, including stakeholders who will implement the RO Model, so that we can ensure that our policy efforts are guided by the real experience of clinicians on the frontlines.

As we noted on the RO Model website[45], the notice of proposed rulemaking proposed that the RO Model would begin on January 1, 2020. As this date has already passed and we have not yet issued a final rule, the RO Model, if finalized, would not begin on this date. If finalized, we would provide information on the effective date of the RO Model in the final rule.

Radiotherapy is a common treatment for nearly two thirds of all patients undergoing cancer treatment[46, 47] and is typically furnished by a radiation oncologist at either a hospital outpatient department or a freestanding radiation therapy center. The RO Model would test whether prospective episode-based payments to physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiotherapy episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Under our proposal, the RO Model would require the participation of providers and suppliers that might not otherwise participate in these models, and would be tested in multiple geographic areas, and would include 40 percent of radiation oncology episodes in eligible geographic areas.

Through discussions with radiotherapy (RT) experts, evaluation experts and actuaries, we determined that a mandatory model would be the best approach to test the proposed episodic payments effectively. Requiring participation in the RO Model would ensure sufficient proportional participation of both hospital outpatient departments and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers or RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model. Testing the Model in this manner would also allow us to learn more about patterns of utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy.

CMS designed the proposed RO Model to qualify as both an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM under the Quality Payment Program. Under the Quality Payment Program, qualifying eligible clinicians who participate in Advanced APMs receive a 5 percent lump sum APM Incentive Payment. We estimate that 82 percent of participating clinicians would receive the Advanced APM Incentive Payment under the proposed RO Model at some point during the model performance period, and those who do not qualify could be eligible for MIPS under the APM scoring standard.

Currently, Medicare uses two different payment systems to pay for radiotherapy services provided in hospital outpatient departments and for the same radiotherapy services provided in free-standing radiation therapy centers. Because of differences in these two payment systems, without the waiver included in our RO Model proposal, clinicians furnishing services in freestanding radiation therapy centers would have their APM Incentive Payment calculated based on both professional and technical episode payments, while clinicians furnishing services

[45] The RO Model website can be accessed at: https://innovation.cms.gov/initiatives/radiation-oncology-model/.
[46] Physician Characteristics and Distribution in the U.S., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.
[47] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

in hospital outpatient departments would have their APM Incentive Payment calculated based only on the professional episode payment. We believe this potential difference between how technical episode payments are treated would create potentially misaligned incentives among RO Model participants. Specifically, we believe that there could be an incentive for participants to shift the setting in which they furnish radiotherapy services from hospital outpatient departments to freestanding radiation therapy centers in order to increase the amount of technical component payments that they receive, resulting in unwarranted increases in their APM Incentive Payment amount. We believe this would prejudice the model testing of site neutral payments.

We explained in the proposed rule that we had determined that 40 percent of eligible episodes in eligible Core Based Statistical Areas nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test, and that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model. RO Model participants treating beneficiaries with one of 17 included cancer types would receive prospective, episode-based payment amounts for radiotherapy services furnished during a 90-day episode of care, instead of regular Medicare Fee-for-Service payments. Participant-specific payment amounts would be determined based on proposed national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. CMS would further adjust payment amounts by applying a discount factor. The discount factor, or the set percentage by which CMS reduces an episode payment amount, would reserve savings for Medicare and reduce beneficiary cost-sharing.

The goal for this Model is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for RO Model participants. We believe the proposed Model would further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer.

The Honorable Susan W. Brooks (R-IN)

1. **Administrator Verma, Approximately 3 million Medicare beneficiaries take the drug Coumadin and rely on regular blood tests to monitor their levels of clotting factor to reduce their risk of stroke or hemorrhage. For many patients, home testing has been a patient-friendly option to minimize lab or physician office visits. Patients who self-test have been demonstrated to achieve improved therapeutic management, resulting in fewer hospitalizations, reduced occurrence of stroke, and reduced drug related complications. Despite the importance of regular testing for many patients, CMS has reduced reimbursement for self-testing by 35% since 2017. The reimbursement reductions occurred because the pricing for testing in the home is being calculated as if it was done in a physician's office which does not account for indirect costs such as**

those associated with home visits, additional capital equipment to allow for each patient to have a testing device in the home and continued patient follow-up calls.

Do you agree that we should be looking for ways to promote home based care options when appropriate rather than pushing patients into less convenient clinical settings, especially if that change causes compliance to suffer, resulting in increased medical costs?

CMS Response: CMS is committed to strengthening the Medicare program by providing seniors more choices and lower cost options in making the best decisions on their care, including allowing services to be furnished in the home when appropriate.

The prothrombin time (PT) test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the International Normalized Ratio (INR), are the standard measurements for therapeutic effectiveness of oral anticoagulant, or blood thinners, such as Coumadin. Medicare coverage for the at-home version of these tests started in 2002 under a national coverage determination. These tests are generally furnished monthly.

Starting in the calendar year (CY) 2018 Medicare Physician Fee Schedule (PFS) final rule, CMS adjusted the payment for these tests two different times in two different ways. These two adjustments are being phased-in simultaneously over several years. The first reduction was based on the American Medical Association's Relative Value Scale Update Committee recommended new direct medical resource inputs for use in pricing the services, and incorporated information from commenters in setting a final rate. The second reduction was in CY 2019, when CMS finalized new prices for a broad range of medical supply and equipment items, including PT/INR supplies. The price adjustments were informed by independent market research and incorporated information from commenters.

We have now heard from stakeholders that the overall price for these services is low because CMS is not accounting for all of the indirect (for example, overhead and other administrative) costs involved in furnishing these services compared to other PFS services. Stakeholders note that because their business models rely on a small set of services, they are unique compared to others who bill under the PFS.

CMS generally does not conduct a separate surveys of the indirect costs for individual specialties or services. Instead, we use survey data on specialty-level indirect practice expense incurred per hour. In this way, we have data for all specialties. Because these services do not have their own specialty code, CMS uses data from a broad range of suppliers for diagnostic tests to develop indirect expenses used in pricing for these codes.

2. **Administrator Verma, the SUPPORT Act which passed last year contained a number of items which required your team at CMS to implement – two examples which were aimed to help Medicare patients reduce opioid use by providing information on the**

range of therapies available to manage chronic pain— the Medicare & You handbook and the Welcome to Medicare physical assessment. In the coming months, CMS will release the revised Welcome to Medicare physical assessment. Could you please discuss/confirm that the assessment will contain information to help seniors with chronic pain and guide them towards non-opioid pain management therapies and navigate their needs towards the appropriate healthcare provider?

3. **Administrator Verma, last year, the SUPPORT Act contained numerous provisions to help Medicare patients manage chronic pain to work towards reducing opioids. Do you feel CMS is on track to complete implementation? Can you please provide an update on the work CMS has done to implement the SUPPORT Act?**

4. **We will never successfully address the opioid epidemic unless we also improve pain management and patient access to non-opioid therapies. That's why Rep. Kennedy and I sponsored Section 101 of CARA which created the Pain Management Best Practices Task Force. What is CMS doing to implement the Task Force recommendations to improve pain care?**

5. **The CMS Roadmap for combatting the opioid epidemic highlights the need to promote non-opioid pain management therapies. Has CMS considered using CMMI to test and collect evidence on effectiveness of non-opioid alternatives for pain management?**

CMS Response to 2-5: As of September 2019, CMS fully implemented 11 sections of the SUPPORT Act. These include issuing Medicaid non-opioid pain guidance and issuing $50 million in grants to 15 states through a demonstration project to increase substance use provider capacity in the Medicaid program as required by section 1003 of the SUPPORT Act. Also, CMS has also worked with state Medicaid programs to ensure they have the tools they need to address the opioid crisis. As an example, to date, CMS has approved 27 section 1115 demonstrations, which have permitted states to expand their full continuum of care for opioid use disorder and substance use disorder treatment.

<u>The Honorable Jeff Duncan (R-SC)</u>

1. **The Agency for Health Care Research and Quality's (AHRQ) National Scorecard on Hospital-Acquired Conditions (HAC) Updated Baseline Rates and Preliminary Results 2014-2017 showed pressure ulcers/injuries as the only HAC whose incidence rate increased during this time span. The negative impact of the hospital acquired pressure ulcers/injuries crisis increases human suffering and costs to the health care system with avoidable injuries. Specifically, HAC/injuries are reported to have led to the death of more than 60,000 hospital patients each year. Please describe the specific steps the Centers for Medicare and Medicaid (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) have taken in the past year, and are planned over the next year, to significantly reduce prevalence of hospital acquired pressure ulcers/injuries? Further,**

I understand that in November 2019 the updated International Guideline on Pressure Ulcer/Injury Prevention and Treatment will be released. It is an evidence-based guideline developed with the support of 14 international organizations that reviewed over 3,500 abstracts. How does CMS plan to work with these organizations to facilitate the adoption of this updated guideline to serve an improved standard of care?

2. **Does CMS or CMMI currently have any new payment and health care service delivery models it is working on or being piloted to provide incentives to providers and clinicians to reduce the human suffering and cost associated with the increasing number of hospital acquired pressure ulcers/injuries?**

CMS Response to 1 and 2: CMS is committed to ensuring beneficiaries have the highest standard of care, and we work to make sure providers are incentivized to prevent hospital-acquired conditions, including pressure ulcers and injuries. CMS has added quality measures addressing pressure ulcers to our quality reporting and value-based payment programs. In the hospital setting, the *Patient Safety and Adverse Events* composite measure provides a performance score based on how often patients have certain complications related to inpatient hospital care, including pressure ulcers. This composite measure is publicly reported on Hospital Compare and is included in both the Hospital-Acquired Conditions Reduction program and the Hospital Value-Based Purchasing program. In addition, there are quality measures addressing pressure ulcers in all of the quality reporting programs for post-acute care providers, such as long-term care hospitals, nursing homes, and home health agencies.

Typically, Medicare pays for a beneficiary's inpatient hospital care at a higher rate if the patient experiences complications. However, to further incentivize the prevention of certain hospital-acquired conditions, Medicare does not pay these higher rates for complications if the condition was not present on admission and if the condition could reasonably have been prevented through the application of evidence-based guidelines. For example, if a beneficiary is admitted to a hospital for pneumonia and later develops a pressure ulcer (stage III or IV) that could have been prevented, Medicare will pay the standard rate for the inpatient care for pneumonia but will not pay the higher rate for the additional treatment of the pressure ulcer. Medicaid has a similar provision that prohibits states from paying for services related to certain provider-preventable conditions in hospitals. This includes most hospital-acquired conditions selected under the Medicare provision described above, as well as provider-preventable conditions identified in a state Medicaid plan.

The Innovation Center plays an important role in our efforts to improve the quality of care our beneficiaries receive. While there is no Innovation Center model specifically targeting pressure ulcers, all of its models are designed to incentivize health care providers to adopt strategies that improve the quality of care for beneficiaries, which may include strategies that prevent hospital-acquired conditions such as pressure ulcers and injuries depending on the model.

The Honorable Earl L. "Buddy" Carter (R-GA)

1. **I appreciate the work the Administration has done to examine how discounting and rebating for drugs is done in the Part D program in order to re-align incentives to improve patient affordability. With this in mind, I continue to be interested in how voluntary list price reductions for a new class of cholesterol-lowering drugs have impacted insurance plan coverage and affordability for those beneficiaries at risk for cardiovascular disease. Given the importance of encouraging these types of price reductions, I'm interested in understanding what types of tools HHS/CMS can use in order to ensure patients benefit from these actions. While CMS made some pronouncements preventing plans from placing these drugs on specialty tiers in 2020 there is a worry that patients will still struggle with affordability due to placement on non-preferred tiers that require patients to pay substantial out of pocket coinsurance costs as high as 50%. If patient access and affordability has not improved or conversely program costs have not declined, what tools are available to the agency (e.g. guidance or written communications from HHS to the plans/PBMS) to improve patient affordability and program costs?**

CMS Response: Manufacturers of a new class of cholesterol-lowering drugs, PCSK9i, introduced new pricing arrangements with high and low cost versions that offered new opportunities for Part D sponsors to develop their formulary and benefit offerings. For calendar year 2020, the PCSK9i medications are not specialty tier eligible. However, Part D sponsors are permitted to determine which tier (e.g. preferred or non-preferred) to place a drug on, so long as the formulary complies with CMS's regulations and is otherwise approved by CMS. To ensure that formularies do not substantially discourage enrollment of certain beneficiaries and to ensure appropriate access is provided with respect to drugs or drug classes as addressed in widely accepted treatment guidelines, CMS annually reviews plan formularies, including formulary tiers. We are committed to addressing prescription drug costs and will continue to examine our Part D policies in order to improve patient affordability and access.

Medicare beneficiaries also have the opportunity to shop during Open Enrollment each year for drug plans that are competing on quality and cost. Prescription drug plan costs and benefits can change from year to year, so we encourage beneficiaries to review their coverage options each year in order to choose the best, most cost effective plan that meets their health needs.