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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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November 8, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, October 23, 2019, at the hearing entitled "Sabotage: The Trump Administration's Attack on Health Care." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from me and other members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, November 22, 2019. As previously noted, your response to the questions in this letter will be included in the hearing record. Your responses should be transmitted by email in the Word document provided with this letter to Benjamin Tabor with the Committee staff (benjamin.tabor@mail.house.gov). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Mr. Tabor at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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.

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?

   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?

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.

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?

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?

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

   a. 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 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?

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?

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?

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

    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?

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?

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?

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?

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.

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)?

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?

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?

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?

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?

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?

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?

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?

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?

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 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?

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?

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

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 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?

    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?

13. 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?

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?

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?

The Honorable Jeff Duncan (R-SC)

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?

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?