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Congress of the United States

U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS

1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625

Washington, DC 20515-6348

<http://waysandmeans.house.gov>

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

Dear Administrator Verma:

Over the course of the past 18 months, this Congress and the Administration have expressed an increased interest in reducing the ever-growing burdens faced by our Nation's health care providers. This burden is in large part due to government regulations that can amount to thousands of pages a year. Not surprisingly, all of this regulation has not bent the health care cost curve, and if we continue on this unsustainable path, by 2026 we will be spending one in every five dollars on health care.¹ Following stakeholder roundtables through the Ways and Means Committee's Medicare Red Tape Relief Project and the Administration's Patients over Paperwork initiative, the path forward from these listening sessions diverges as the Committee looks to potential legislative solutions and the Administration takes aim at reducing burdens through the annual regulatory process. We are writing to applaud the Administration's efforts in this area as well as provide our feedback on specific ways to strengthen these efforts toward burden reduction, in each of the specific proposed rules laid out below.

Over the last several weeks, the Centers for Medicare and Medicaid Services (CMS) has released the following proposed regulations that contain policies related to burden reduction:

- Physician Fee Schedule (PFS)
- Outpatient Prospective Payment System (OPPS)
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and End-Stage Renal Disease (ESRD) Payment Systems
- Overhaul of Medicare's Accountable Care Organization (ACO) Program

¹ "National Health Expenditure projections 2017-2026," Cms.gov, February 2018, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpData/Downloads/ForecastSummary.pdf>

We will review our thoughts on each of these regulations in turn below. We continue to hear about issues such as physicians spending nearly two out of every three hours on additional paperwork²; medical product makers finding it harder to serve Medicare patients; and medical equipment suppliers having trouble getting equipment to all the patients that need them. These regulatory burdens and barriers do not reflect the intent of programs passed by Congress. While there is undoubtedly a need for regulations to implement new policies, we firmly believe that such regulations must replace old ones, not continue to be layered upon one another. A Washington-based top-down approach is harmful for the entire system from providers to patients, and as such we commend your commitment to including Requests for Information (RFIs) in each rule, particularly around the transparency in health care costs and efforts to combat the opioid crisis.

Physician Fee Schedule (PFS)

As the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 continues to be implemented and we head into the first payment adjustment year for clinicians participating in the Merit-Based Incentive Payment System (MIPS), it is more important than ever that the PFS help to ensure the success of the new physician quality payment program (QPP) by reducing any unnecessary burden. Congress' intent in passing MACRA was to reduce burdens while increasing quality and value in how physicians are paid. We appreciate the recent actions you have taken both on implementing that intent (including the changes to add flexibility for CMS in the Bipartisan Budget Act of 2018 (BBA '18)) and reducing burdens in other areas of the PFS, including:

- Reducing unnecessary or overly burdensome reporting measures in MIPS;
- Revamping the reporting requirements surrounding electronic health records to align with modern technologies and the need for a speedier path to interoperability;
- Utilizing CMS flexibilities to make the implementation of the QPP gradual enough to ensure success and participation;
- Creating the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration, thus allowing clinicians who serve a sufficient number of patients in arrangements with Medicare Advantage Organizations (MAOs) to be eligible for waivers from MIPS;
- Adding service codes to expand remote telehealth patient access and allow for virtual check in through phone, electronic-visual communication, and texted images; and
- Removing unnecessary "functional status" reporting requirements for therapy.

We once again commend you on the RFI on Stark Law modernization. As we have previously discussed with the Agency and through the Health Subcommittee's Hearing on modernizing Stark Law, the success of our push towards higher value, coordinated care requires a concerted effort to remove barriers to providers' working together along the continuum of care.

Additionally, we applaud the Administration's efforts to streamline the clinician enrollment process for Medicare. Bringing these systems into the 21st Century will truly lower provider

² C. Sinsky and L. Cooligan et al., "Allocation of Physician Time in Ambulatory Practice: A Time in Motion Study in Four Specialties," *Annals of Internal Medicine*, December 2016, <http://annals.org/aim/article-abstract/2546704/allocation-physician-time-ambulatory-practice-time-motion-study-4-specialties>

burden as well as expedite enrollment, which is a necessity as we face shortages in professional medical services, particularly in rural areas.

While that proposal contained many meaningful changes, we urge you to more closely consider the following policies contained in the proposed rule:

- Reducing the number of evaluation and management coding categories from five to two, which supports the spirit of burden reduction, may be an oversimplification that could result in unintended consequences. We ask that you take a more deliberate approach working with stakeholders, and consider a policy with at least three coding categories, including considerations such as patient risk scores in addition to time spent, to ensure higher levels of accuracy while still reducing burdens.
- Changing the amount the program pays for new drugs from wholesale acquisition cost (WAC) plus 6 percent to WAC plus 3 percent, which without any lead-time could create incentives to use less innovative drugs under our current payment systems. These changes may be more valuable with additional considerations to the average sales price (ASP) methodologies.

Another issue that we have heard from every stakeholder in the clinician community about is prior authorization. Nationally, clinicians are facing delays in furnishing care to patients, whether it be services or drugs, due to prior authorization guidelines that are perceived to be overly stringent. While the benefits of prior authorization by health plans are clear – including improved program integrity and reductions in overspending – we have serious concerns that these programs are causing unnecessary delays in patient care. One particular area of concern is prior authorization for items that are regularly reordered for patients, such as diabetic supplies. We look forward to working with you and the Administration on a middle ground that will both uphold program integrity standards while avoiding undue burden on providers and patient access to needed care.

Finally, in an effort to reduce burdens and barriers to provider participation in various programs, including MIPS, we ask you to further address an issue of reporting consolidation. Over the next few years, physicians are expected to report under several different methods varying by specialty. Specialties participating in qualified clinical data registries (QCDR) or appropriate use criteria (AUC) should be given an opportunity to report in a singular fashion under MIPS. We urge CMS to take steps to create a uniform system in order for this to occur.

Outpatient Prospective Payment System (OPPS)

We applaud the Administration for taking action through the OPPS proposed rule, which was released along with updates to the Ambulatory Surgical Center (ASC) payment changes. Over the course of the last decade, payments to ASCs have fallen compared to outpatient hospitals. As such, we appreciate actions that you have taken to provide regulatory relief as well as reduce some of the disparities in payment between different sites of service. However, we also urge caution to avoid creating any new barriers while providers are working to enter into arrangements to increase value-based care and improve patient outcomes through greater coordinated care. As you finalize these proposals we also urge you to consider the possible disruption to those providers who are already carrying this risk and leading by example. These

leaders in health care may require redesigning their models, resulting in potential delays in achieving savings and better outcomes.

Specifically, we applaud the following policies included in the OPSS proposed rule, many of which are an important step towards reducing burdens:

- Promoting price transparency for patients when deciding a site of care;
- Synchronizing ASC payment with outpatient hospital updates by using market basket updates instead of CPI-U;
- Expanding the ASC approved procedures list;
- Expanding transparency around decision making over the approval of these codes;
- Expanding the use of the new technology add on payment by creating categories of payment for low-volume devices that don't meet current requirements;
- Proposing policies to combat the opioid crisis -- including a separate payment for non-opioid pain management medications -- to encourage the use of therapies that avoid any chance of addiction; and
- Decreasing unnecessary or overly burdensome reporting provisions such as streamlining duplicative reporting measures and eliminating those that no longer make sense.

While we understand that payment changes throughout these systems will always have consequences elsewhere due to budget neutrality requirements, we urge you to carefully review policies that could have the unintended consequence of pushing vulnerable patients to higher cost settings.

Finally, we ask that you continue to fully consider stakeholder input during the comment period on provisions that could add burden rather than relieve it.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and End-Stage Renal Disease (ESRD) Payment Systems

DME and POS are inextricably related, tied together under one payment system as different as the two types of medical equipment are in statute and in practice. From everyday medical equipment such as walkers and knee braces to wheelchairs and equipment assisting patients with breathing in their homes, there is no doubt that this benefit is crucial for Medicare beneficiaries. However, over the course of 30 years and in particular the last seven years, regulations have hindered innovation and a payment system that has become anything but competitive has decreased the number of suppliers by over 40 percent. That has left many parts of the country, particularly rural areas, looking for answers as they consider the future of access to DME.

In a similar vein, innovation in ESRD treatment has been scarce in the 46 years since the ESRD coverage and payment system was added to the Medicare program. Despite significant innovation in the medical technology field, we are concerned that CMS regulation and the lack of flexibility in a rigid payment bundle have drained most if not all incentives to innovate in this area.

We greatly appreciate this Administration's acknowledgement that the implementation of the DMEPOS competitive bidding program has the potential to cause patient access issues. We

applaud your goal of moving to a more competent and competitive bidding system for these products. We also applaud the following provisions in the proposed rule that seeks to reduce burden and increase innovation for both DMEPOS and ESRD treatment:

- Continuing relief for rural and non-competitively bid areas and replacing the current competitive bidding system with one that limits burden and will reimburse fairly and avoid price distortion;
- Enacting a transition period before starting the new DMEPOS payment methodology; and
- Allowing more flexibility through expanding the use of the Transitional Drug Add-on Payment Adjustment (TDAPA) for new drugs outside of the ESRD bundle to ensure that innovators seek participation in the market.

While we appreciate these reforms to the DMEPOS programs discussed above, we ask that you ensure that all areas in our nation see relief as we transition to a new system. It is crucial to any fresh start that the playing field be set in a fair manner to avoid the over-correcting and re-correcting required through both regulatory and congressional action over the last seven years.

Specifically, we believe strongly that lead item pricing will reduce the complexity of the competitive bidding process by reducing the number of items on which suppliers have to submit bids. However, we caution that being overly-restrictive in the amount of lead items, or tying the pricing rations of these items to older fee schedules into perpetuity, may in the end undermine the great efforts to reduce burdens and increase access in this rule.

We also ask that you consider allowing innovative products that are still on the market and have previously been left out of TDAPA to qualify in order to help spur stakeholders to innovate in assisting in the care of our most vulnerable patients. Physicians should be in the driver's seat in deciding appropriate methods of care, not regulations and outdated bundles. Allowing patients to immediately access these products to improve care and quality of life will lay a strong foundation for new products approved by the FDA as set forth in the proposed regulation.

Overhaul of Medicare's Accountable Care Organization (ACO) Program

We welcome efforts to revamp Medicare's ACO program, which grew out of the shared savings demonstrations under the George W. Bush Administration. In 2006, then CMS Administrator Mark McClellan said of these shared savings demonstrations, "Physicians know this is the right thing to do for their patients, and now Medicare is providing better financial support to help make it happen, rather than just paying more for more services."³ The changes in this proposal truly highlight the original intent of these arrangements and build upon the positive direction in which the ACO program has been headed in recent years.

It is important that the ACO program reward those who truly are improving care through coordination and doing so while creating efficiencies that might reduce unnecessary spending in the Medicare program writ large. However, we also recognize a central point in this proposal -- that participation must include all parties carrying risk, or having "skin in the game." This key

³ <https://www.cms.gov/newsroom/press-releases/medicare-expands-opportunities-physicians-earn-performance-payments-improving-quality>

care for patients -- is central to our work in Congress. This is clearly displayed in recent statutory changes to improve ACO's flexibilities and ability to participate in such proven care improvement strategies as expanded telehealth and improved visibility into the patient population.


We appreciate the Administration's following actions to implement recent Congressional directives and other policies that remove needless barriers harming ACO participation and that will lead to higher levels of managed care in Medicare:

- Beginning to implement the ACO provisions from BBA '18 that would:
 - Allow for prospective assignment;
 - Expand the use of telehealth for physicians participating in the ACO; and
 - Allow for ACOs to provide patients with rewards up to \$20 for each qualifying high value primary care service;
- Preventing a massive exit of ACOs from the program by allowing for current Track 1 ACOs whose contracts are ending in 2018 to have a 6-month extension as they apply for a new performance contract; and
- Considering how the program could allow for beneficiaries to opt-in to high value ACOs as well as expand incentives for ACO activities that will combat the opioid crisis.


As you consider stakeholder comments for this proposal, we ask that you bear in mind one impactful issue all ACOs and health care providers must weigh in judging participation in this program and taking on risk: stability. As new contracts for shared savings arrangements are drawn up, we ask that a component of these negotiations include some level of regulatory and payment stability for the length of the agreement across all aspects of Medicare. We also ask that you reconsider the reduction in the shared savings amount down to 25 percent, as this may also hinder an ACO from being financially able to take on higher levels of risk.

We thank you again for prioritizing reducing red tape and paperwork burdens for all providers who furnish care to patients. We appreciate your consideration of our views and look forward to working with you on next steps to both reduce unnecessary regulations and put patients first in our health care system.

Sincerely,



KEYVIN BRADY
Chairman
Committee on Ways and Means



PETER J. ROSKAM
Chairman
Subcommittee on Health
Committee on Ways and Means

CC: The Honorable Mick Mulvaney
Director
White House Office of Management & Budget

CC: The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services