

May 8, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Committee on Energy and Commerce
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

On behalf of the physician and medical student members of the American Medical Association (AMA), I applaud the dedication and leadership that you and the Committee have demonstrated by working in a bipartisan fashion and engaging stakeholders so that we are able to accelerate the discovery, development, and delivery cycle that will save lives. The AMA appreciates the opportunity to provide comments on this draft of the “21st Century Cures Act” (Cures). Your efforts to focus this draft legislation is a welcome development, and I have highlighted below the provisions of the legislation that are of keen interest to practicing physicians and that will have a positive impact on their patients’ health outcomes.

Section 3041. Exempting From Manufacturer Transparency Reporting Certain Transfers Use for Educational Purposes

Regular, unrestricted access to independent, high quality information on the latest clinical innovations that are relevant to improved patient health outcomes is the lifeblood of medical practice for physicians and directly benefits patient outcomes. The AMA strongly supports Section 3041, which would exclude manufacturer payments for medical textbooks, medical journal reprints, and independent continuing medical education (CME) as a reportable transfer under the Physician Payment Sunshine Act (Sunshine Act). While the Centers for Medicare & Medicaid Services (CMS) has recently clarified in its subregulatory guidance that manufacturer transfers of funds to support independent CME are not subject to reporting, the Agency has not revised its position on medical journal reprints and medical textbooks. This section of the Cures Act would not only remedy this interpretation of the Sunshine Act which is contrary to the original congressional intent, it would also ensure that the Agency does not issue any additional regulatory changes on the issue of independent CME.

Section 3081. Improvements in the Medicare Local Coverage Determination

Accelerating cures is only meaningful if patients are actually able to obtain access to the innovations that are fueled by the investment in research and incentives to translate into clinical practice. There remain significant barriers to access for not only 21st Century cures, but 20th Century cures for Medicare beneficiaries. The AMA strongly supports Section 3081, which would require Medicare contractors to comply with the local coverage determination (LCD) process that is designed to improve the transparency of the LCD process. The AMA urges the Committee to make the provision effective upon enactment of

the 21st Century Cures and encourages the Committee to codify additional LCD notice, process, procedure, and substantive requirements.

NIH Funding Support

Discovery and translational research continue to drive advancements in medical care. The AMA supports increased funding for the National Institutes of Health to support the rapid development of testing and treatments that improve and often save lives.

Section 3021. Telemedicine

The AMA strongly supports the Committee's efforts to remove restrictions on Medicare coverage of telemedicine services that limit beneficiary access to telehealth services with a strong clinical evidence base. Specifically, the AMA supports removing Medicare geographic restrictions on coverage of telemedicine services; allowing dual eligibles to benefit from such services where Medicaid programs cover telemedicine; and removing all Medicare telemedicine restrictions in the context of alternative payment models. The AMA also recommends that the Committee include a technical modification which would allow CMS to consider concurrently new CPT codes for adoption and coverage as a telehealth service. (The Agency currently has to include the CPT code on the relevant fee schedule and wait until the subsequent year to include it as a covered telehealth service.) The AMA opposes federal legislation that would preempt or waive licensure and medical practice laws for telemedicine encounters and strongly affirms that physicians must be licensed in the state where the patient receives services.

Section 3001. Interoperability

The AMA appreciates that the Committee continues to consider proposals to achieve interoperability. In order to achieve interoperability, key foundational issues must first be established. We would encourage the inclusion of language that addresses the following:

Interoperability Cornerstones

- **Direct the Administration, by the next certification cycle, to begin development of provider directories and facilitate patient matching.** Developing these tools will ensure that when exchanging information among records that the intended recipient and patient are easily and correctly identified.
- **Provide immediate funding for coordinating standard terminologies and vocabularies.** A common understanding of the definition of what is being sent and the application of a standard format are prerequisites for interoperability.
- **Clinicians Use of Clinical Terms for day-to-day patient care.** Standardizing such clinical data definitions should be primarily driven by a multi-stakeholder physician-led organization that is a leader in quality improvement, outcomes, and performance measurement with coordination support provided by CMS and the Office of the National Coordinator for Health Information Technology (ONC).
- The government should coordinate the development of a migration strategy for competing standards when shown to be incompatible with a timeline and benchmarks for resolving inconsistencies, such that they occur.

- **Identify priority use cases.** Rather than specifying the type of technology that is needed to exchange patient information, Congress should direct the Administration to develop high priority use cases that are used daily by physicians to coordinate care. For example, ONC should focus on closing the referral loop by having Electronic Health Records (EHRs) demonstrate that the office note/discharge summary and other commonly used data elements actually make it to the intended recipient regardless of the type of technology used.

Transparency and Enforcement

- **Require that EHR systems pass robust interoperability testing using common standards.** Such standards should be developed in conjunction with the private sector, and could include the ability to connect with multiple Health Information Exchanges (HIEs) or compliance with private-sector testing requirements.
- **Publicize failure rates for all future testing of certified EHRs in a common format that is easily discernable.** There are hundreds of certified products and providers should not be expected to have to comb through hundreds of pages of information that is hard to understand. A direct apples-to-apples comparison will help physicians, hospitals, and other purchasers make more informed choices and can lead to a more naturally competitive marketplace.
- Fund efforts for post certification surveillance by ONC to track interoperability, how well systems perform, and patient safety in the real world after products have been deployed.
- Prohibit the use of “gag clauses” in EHR contracts that prohibit providers from openly discussing problems with their systems.
- Require ONC to conduct a survey of providers that evaluates barriers to interoperability, including costs.

We would further note that the constraints of the Meaningful Use (MU) program are directly tied to the lack of interoperability. Vendors and physicians are focused on meeting the complex requirements of MU and often do not have the time and resources to focus on actions that fall outside of the numerous MU measures—including interoperability. Allowing flexibility in the MU requirements and creating a shorter MU reporting period would allow for innovation and a focus on data exchange that could rapidly lead to greater interoperability across EHRs and other health IT.

Section 3151. Medicare Part D Lock-In

The AMA remains concerned with proposals that lock beneficiaries into pharmacies/providers at the sole discretion of prescription drug plans with no meaningful consultation with the beneficiary’s physician or information on the beneficiary’s health status, illnesses or injuries, or treatment plans prescribed by their physician(s). Medicare Prescription Drug Plans (PDPs) do not possess this information nor does the proposal require them to have it before a beneficiary is locked in. PDPs would be free to lock beneficiaries into pharmacies selected by the plan with absolutely no evidence that the beneficiary is inappropriately utilizing controlled substances. This strips Medicare beneficiaries of their choice of provider and can affect access to necessary treatments with serious potential consequences for their health status.

We are concerned with turning over important clinical functions to PDPs given the considerable impact they might have on beneficiary health and well-being and the questionable track record of PDPs to adequately carry out these functions. CMS has identified serious shortcomings in PDP operations that

adversely affect beneficiaries. The 2013 Program Audit Review by the Medicare Parts C and D Oversight Enforcement Group found serious and recurring conditions in PDP operations, including:

Of 28 Part D Sponsors audited on Formulary and Benefit Administration:

- 61 percent failed to properly administer CMS-approved formulary policy by applying unapproved quantity limits;
- 50 percent failed to properly administer CMS-approved formulary policy by applying unapproved utilization management practices;
- 43 percent failed to properly administer CMS transition policy;
- 39 percent improperly effectuated a prior authorization or exception request; and
- 32 percent failed to provide a continuing beneficiary a transition supply of a non-formulary medication.

Of 27 Sponsors audited on Coverage Determinations, Appeals, and Grievances:

- 89 percent failed to provide beneficiaries and prescribers with adequate and/or accurate rationale for denial;
- 78 percent did not demonstrate sufficient outreach to the prescriber or beneficiary to obtain information necessary to make an appropriate clinical decision;
- 59 percent misclassified a coverage determination or redetermination request as a grievance and/or customer service inquiry;
- 56 percent did not notify the beneficiary or their prescriber, as appropriate, of its decision within 72 hours of receipt of a standard coverage determination request or, for an exceptions request, the physician's or other prescriber's supporting statement; and
- 56 percent made inappropriate denials when processing coverage determinations.

In terms of proposed appeal rights, the track record here provides little confidence. In fact, many providers and beneficiaries have completely given up on the current appeals options available. CMS audits of Medicare Part D (Part D) appeals show why. Plans have little incentive to properly handle appeals and the consequences for failing to do so are minimal. Massive failures have been cited by CMS for failure to provide adequate explanations of denials, failure to conduct adequate outreach and provide required notice. Frequently, appeals are classified by plans as complaints with no further action taken.

In its March 2014 Report, MedPAC noted:

“Our focus groups with beneficiaries and physicians and interviews with beneficiary counselors revealed general confusion and frustration with the process. For example, the majority of beneficiaries were not aware that they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works. Physicians often found plan exceptions and appeals processes frustrating, noting that some plans' processes are particularly burdensome. Beneficiary counselors reported that they treated the exceptions and appeals process as a last option and often helped beneficiaries find alternative ways to access their medications—for example, by directing them to manufacturers' assistance programs. While the exceptions and appeals process must ensure that exceptions are granted only for clinically appropriate cases to protect the tools that plans use to manage the benefit, these findings suggest a need for increased

transparency and streamlining of the processes involved so that beneficiaries and physicians are not discouraged from seeking exceptions for needed medications.”

In contrast to the proposal to lock beneficiaries into a single pharmacy and/or provider, the current Overutilization Monitoring System (OMS) offers the preferred pathway for addressing concerns of potential abuse by Medicare beneficiaries, including meaningful consultation with a beneficiary’s physician(s) before more restrictive measures are allowed. PDPs are currently provided quarterly reports on enrollees who meet certain CMS criteria, such as the number of pharmacies where they fill prescriptions for opioid analgesics and the number of prescribers who prescribe these drugs to them. Plans are then expected to consult with patients’ physicians to determine if all of the prescriptions and doses are medically appropriate or need to be adjusted or, for example, if a prescriber was not aware that the patient was receiving multiple controlled substance prescriptions from different physicians.

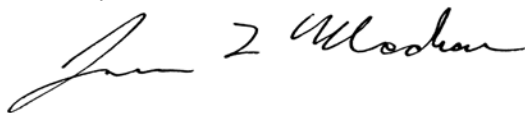
Though the OMS program only began in 2013, it has shown significant results. According to CMS, “[c]omparing recent data with 2011 Part D data that pre-dates the implementation of the monitoring system shows that there has been a substantial reduction in the number of opioid and acetaminophen overutilizers in Medicare Part D.” In 2011, more than 172,000 Part D enrollees were identified as meeting CMS criteria for potential opioid or acetaminophen overutilization. Between January and June 2013, the number of Part D enrollees with potential opioid or acetaminophen issues dropped to approximately 35,600 – a rate that would represent a reduction of nearly 60 percent if maintained throughout 2013.

Even here, though, there is room for improvement. In the 2015 Call Letter, CMS noted that fully 67 percent of potential opioid overutilization responses from the plans reviewed in the January 2014 OMS reports were reported as “BSC-No further review planned; Beneficiary did not meet the sponsor’s internal criteria.” CMS noted “It appears that some sponsors’ criteria or processes to identify and address potential opioid overutilization may be insufficient.”

Instead of adding yet another duplicative federal program to address potential drug diversion and abuse, CMS, providers, and plans should be working to ensure that the current programs, such as OMS, are being implemented appropriately and effectively. While engaging physicians and other prescribers in discussions about the appropriateness of particular treatments requires a deeper commitment of time and resources on the part of PDPs, we believe that it is clearly superior to allowing unilateral actions by plans without sufficient information on a beneficiary’s health or treatment plans.

The AMA appreciates the opportunity to provide comments on the 21st Century Cures initiative and looks forward to working with you and the Committee to ensure the proposed policies support and promote physicians’ ability to practice medicine in the innovative health care environment of the 21st Century through new technologies and cures.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD