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Medicare Red Tape Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date:	August 25, 2017
Name of Submitting Organization:	Alliance of Specialty Medicine
Address for Submitting Organization:	3823 Fordham Rd NW, Washington, DC 20016
Name of Submitting Staff:	Vicki Hart
Submitting Staff Phone	(202) 729-9979
Submitting Staff E-mail:	info@specialtydocs.org

Statutory___ Regulatory_X__

Please describe the submitting organization's interaction with the Medicare program:

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Short Description: Two Midnight Rule

Summary:

When a patient arrives at a hospital, he or she can be admitted or put under outpatient observation status, which is meant to determine whether a patient should be admitted or discharged. Under observation status, **hospitals** receive reimbursement through Medicare Part B, which covers physician care and is typically lower than rates for inpatient care covered under Part A. Beneficiaries can experience higher out-of-pocket costs than they would as inpatients. Patient status also affects whether Medicare will cover care in a skilled nursing facility (SNF) after discharge since Medicare will only cover SNF care for beneficiaries who have been hospital inpatients for at least three consecutive days.

Concerned about not being reimbursed at all if they admitted beneficiaries who should have been placed put under observation status first, the percentage of observation cases for beneficiaries lasting longer than 48 hours more than doubled between 2006 and 2011, raising concern among federal officials. As a result, CMS implemented the Two-Midnight Rule through the 2014 Medicare Inpatient Prospective Payment System Final Rule, with the objective of clarifying when a hospital inpatient admission is appropriate under Medicare. The rule states that "for those hospital stays in which the physician expects the beneficiary to require care that crosses two midnights and admits the beneficiary based upon that expectation, Medicare Part A payment is generally appropriate." Alternatively, inpatient rates are “generally inappropriate” when a physician expects a beneficiary to have a hospital stays lasting less than two midnights.

This policy was intended to reduce improper payments for short inpatient stays, inconsistent use of inpatient and outpatient stays among hospitals, and the number of Medicare beneficiaries who had long outpatient stays and thus didn’t quality for skilled nursing facility services. However, this controversial policy was repeatedly delayed due to concerns that it undermines clinical decision-making. As early as 2014, the American Hospital Association (AHA) filed two federal lawsuits challenging the rule and members of Congress proposed the elimination of the rule. Furthermore, in 2015, the Medicare Payment Advisory Commission (MedPAC) earlier voted to approve a set of recommendations that included ending the two-midnight rule.

In December 2016, the HHS OIG issued a report titled, “Vulnerabilities Remain Under Medicare’s 2-Midnight Hospital Policy,” which found that although inpatient stays have decreased since Medicare established the two-midnight rule, several weaknesses remain in the policy. The OIG found five vulnerabilities still exist:

- Medicare pays more for some short inpatient stays than for short outpatient stays even though the hospitalizations are for similar reasons.
- Hospitals continue to bill for a larger number of long outpatient stays, which causes beneficiaries to pay more in co-payments and limits their access to skilled nursing facility (SNF) services than if their hospitalizations had been designated as inpatient stays.
- Medicare patients pay more for outpatient stays and have limited access to SNF services than they would as inpatients.
- Hospitals still vary in how they use inpatient and outpatient stays.

Related Statute/Regulation:

Social Security Act 1861 (i) [42 U.S.C. 1395x]
https://www.ssa.gov/OP_Home/ssact/title18/1861.htm

42 CFR 419.22 (n)

Proposed Solution:

The 2-Midnight Rule has had significant unintended negative consequences that burden Medicare beneficiaries. It remains an artificial construct reflecting a flawed approach that detracts from the physician patient relationship since it doesn't allow physicians to exercise appropriate clinical judgment when determining whether to admit a patient. It also unnecessarily increases the administrative burden of admitting

physicians and detracts from admission criteria that depend upon clinical judgment. CMS should 1) Rescind the 2-Midnight Rule to allow for clinical judgment in determining a patient's inpatient or observation status; and 2) Count time spent in a hospital as an outpatient toward the three-night requirement for Medicare coverage of SNF services.

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Short Description: Drug Compounding

Summary:

FDA's Insanitary Conditions draft guidance over-reaches to include physician offices as compounding facilities and would prohibit the in-office preparations of drugs, which is often the standard of care for many medications. The draft guidance would set forth new standards (e.g., requiring physicians that compound drugs in their offices to have engineering control devices capable of maintaining an ISO Class 5 environment or be deemed "insanitary") without scientific evidence to suggest this level of precaution is warranted. Moreover, the process under which these new standards are being established circumvent ongoing deliberations to update USP General Chapter <797>, which FDA currently recognizes as required under statute.

FDA draft guidance for 503A traditional compounders prohibits compounding for office use without a patient-specific prescription. Patients with emergent conditions may need immediate treatment in the physician's office with compounded drugs that many outsourcing facilities are not willing to produce.

Related Statute/Regulation:

- *Insanitary Conditions at Compounding Facilities* - draft FDA guidance (August 2016)
- *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act* – final FDA guidance (December 2016)

Proposed Solution:

The Alliance of Specialty Medicine requests that Congress require FDA to withdraw its draft and final guidances, and provide oversight of FDA's regulation of compounded drugs to ensure patients have continued access to these drugs.

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Short Description: Medicare Imaging Appropriate Use Criteria Program

Summary:

Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 (P.L. 113-93) established an appropriate use criteria (AUC) program for advanced diagnostic imaging services provided to Medicare beneficiaries. Per the statute, beginning Jan. 1, 2017, physicians and other health care professionals who order advanced diagnostic imaging tests must consult with federal approved AUC using a federally qualified clinical decision support mechanism (CDSM), and professionals who furnish these tests must document via claims the ordering professional's consultation of AUC in order to be paid for the service. The law also directs CMS to require prior authorization beginning in 2020 for ordering outlier professionals related to specific clinical priority areas.

This program was first introduced in the CY 2016 Physician Fee Schedule (PFS) Final Rule. Additional policies related to this program were included in the CY 2017 PFS Final Rule, including CMS's decision to not require that ordering professionals meet program requirements by Jan. 1, 2017 as specified in law. The 2018 PFS rule proposes that clinicians must begin reporting AUC consultations in 2019, but that services would be paid regardless of whether or not claims submitted for payment include the correct AUC consultation documentation.

The Alliance of Specialty Medicine believes that this program places excessive burden on physicians across a broad range of specialties with little evidence of clinical benefit. CMS continues to work through significant challenges related to the program, as evidenced by its delayed implementation and recent request for feedback on whether additional delays beyond the newly proposed 2019 implementation date are necessary. We also remind Congress that CMS has yet to finalize all of the policies that will enable physician practices to prepare for the program and to make informed practice changes, including investments in CDSMs, updating of reporting and billing systems, and incorporating consultation into practice patterns. The first and limited set of qualified CDSMs were only first announced in July 2017, and it is still unclear to what extent they are easily accessible, applicable, and implementable across practices. In general, the acquisition and implementation of a CDSM that integrates with the clinician's EHR system may be cost prohibitive or hampered by electronic health record (EHR) vendor readiness, thereby increasing administrative burden on clinicians. While the program is required to include at least one free CDSM, these are often web-based or stand alone products that do not easily integrate with EHRs. In fact, a 2015 GAO report found that providers using web-based or stand-alone software applications experienced frustration with the lack of integration between the CDSM and their EHR system and experienced workflow inefficiencies.[1]

Furthermore, the program is duplicative of — and even inferior to — the Quality Payment Program (QPP), which already holds clinicians accountable for quality and patient outcomes (something that the AUC program fails to do), as well as for resource use, including the use of diagnostic tests and procedures. Given the implementation of the QPP, this separate program is redundant, and CMS can readily incorporate the use of AUCs for diagnostic imaging into the QPP.

We also remind Congress that in the coming years, physician practices will be faced with other new federal reporting requirements, including the reporting of patient relationship codes.

1. Considerations for Expansion of the Appropriate Use Criteria Program. United States Government Accountability Office Report to Congress; GAO-15-816. Sept. 2015. http://www.gao.gov/assets/680/672856.pdf

Related Statute/Regulation:

42 USC 1395m(q), as added by the Protecting Access to Medicare Act of 2014
42 CFR 414.94

Proposed Solution:

The Alliance of Specialty Medicine requests that Congress terminate the requirements on ordering professionals to consult AUC and on furnishing professionals to report on such consultation given the duplication and limited value of the Medicare AUC program in light of the QPP. To the extent that Congress needs additional time to investigate the extent of duplication and marginal value of the AUC program, the

Alliance requests that CMS further delay the effective date until at least 2021, or until CMS can adequately address technical and workflow challenges with its implementation and any interaction between the QPP and the AUC requirements.

Commented [CM1]: Note to Alliance reviewers: In the Reg Relief Issue Brief, we focused on a regulatory solution ("encourage CMS to further delay the effective date of the Medicare AUC Program"). Given this is responding toa request coming from the Hill, it may be more direct to ask for a statutory change, particularly since there is an implementation date in statute. However, we welcome edits/recommendations to focus on regulatory changes if that is preferred.

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Short Description:	Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Transition Policies

Summary:

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-Based Incentive Payment System (MIPS) to assess clinician performance across four categories, with each category ultimately contributing to a specified portion of the total performance score: quality (30 percent), resource use (or "cost"; 30 percent), use of certified electronic health records (or "advancing care information"; 25 percent), and adoption of clinical practice improvement activities (or "improvement activities"; 15 percent). Based on performance across these four categories relative to a "performance threshold," clinicians may receive upward or downward adjustments to their Medicare payments starting in 2019.

MACRA provided flexibility to the Secretary of Health and Human Services (HHS) to phase in changes under MIPS during the first two years. For example, MACRA specified that the resource use category weight could be less than 30 percent for the first two years of the MIPS program. Additionally, MACRA provided discretion for the HHS Secretary to set a lower composite performance threshold in the first two years of the program, before ultimately establishing the national mean or median of performance as the performance threshold by year 3.

However, MIPS reflects a significant change in how clinicians are assessed and how their payments are determined. Many clinicians had struggled to stay abreast of previous requirements, or were previously exempt, and MACRA created a whole new and complex regulatory framework, with new rules to understand and new programmatic and administrative requirements that place significant burden on clinicians. Additionally, CMS has experienced challenges with implementation, particularly around the resource use category, and significant work is still underway to not only develop meaningful and applicable cost measures that are also valid, reliable, and actionable by affected clinicians, but also to translate performance on such measures into performance ratings (for example, based on clinicians' relationship to patients). Furthermore, clinicians will not receive information on their performance on final measures for several years, such that they will have limited information on how to target improvement efforts to increase their performance under the resource use category during a transition period.

Related Statute/Regulation:

Resource use category weight: Social Security Act 1848(q)(5)(E)
Performance Threshold: Social Security Act 1848(q)(6)(D)(i)

Proposed Solution:

To address some of these challenges, the Alliance asks Congress to extend the policies that ease the transition to the MIPS framework, specifically by (1) providing the Secretary ongoing flexibility to phase in the resource use category weight and (2) providing the Secretary with flexibility to set the performance threshold at a lower level than the mean or median performance. We ask that Congress provide ongoing flexibility to phase in the resource use category weight until the methodology for assessing and scoring clinicians is fully established and stable, and until clinicians have regular and timely feedback on their performance. Additionally, we request that Congress give the Secretary the flexibility to decide when it would be appropriate to rely on a performance threshold that it lower than the mean or median performance and to require that if the Secretary does choose to rely on the mean or median performance that it at least use the lesser of the two . Furthermore, we request that Congress require the Secretary to cap annual increases in the performance threshold to no more 10 points in order to protect against unreasonable increases in performance requirements from one year to the next.

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Short Description: Application of the MIPS payment adjustment on Part B drugs

Summary:

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-Based Incentive Payment System (MIPS) to assess clinician performance across four categories: quality, resource use, use of certified electronic health records, and adoption of clinical practice improvement activities. Based on performance across these four categories relative to a "performance threshold," clinicians may receive upward or downward adjustments to their Medicare payments starting in 2019. CMS intends to apply the MIPS payment adjustment to Part B drugs, which it believes it is required to do based on its legislative interpretation of Section 1848(q)(6)(E) by its Office of General Counsel (OGC). This means, for example, that physicians who administer Part B drugs will receive a -4 percent reduction on medications they administer to beneficiaries in their offices if they either fail to participate in MIPS or properly "test" MIPS in 2017. The -4 percent reduction is in addition to a -2 percent reduction they already receive due to sequestration. On the flip side, physician practices that do very well in MIPS, especially those that cross the exceptional performance threshold, would receive tremendous bonuses as a result of the drugs they administer.

This policy would have a major impact on several medical specialties who administer Part B drugs in their offices. It is also a significant departure from how CMS has applied payment adjustments in prior programs (e.g., PQRS, MU), where the statute was clear that adjustments should be limited to professional services.

Physician practices that fail in MIPS will not be able to absorb the cuts to the medications they "buy and bill" and could potentially be forced to send patients to hospital outpatient departments (HOPD) for care, which will significantly increase Medicare spending, or worse, force these practices to close their doors permanently.

Related Statute/Regulation:

Section 1848(q)(6)(E)

Proposed Solution:

The Alliance of Specialty Medicine requests that Congress eliminate Part B drugs from the MIPS payment adjustment. MIPS Adjustments should only apply to covered professional services under the Medicare Physician Fee Schedule.

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Short Description: Narrow Provider Networks among Medicare Advantage Organizations

Summary:

Medicare Advantage Organizations (MAOs) plans have adopted narrow or restricted networks to extract payment concessions from network providers or improve performance on quality metrics. This practice diminishes access to medically necessary specialty care services, and in particular, specialists and subspecialists may be excluded based on network availability of their less specialized peers. MAOs continue to exclude certain specialty and subspecialty providers from network adequacy calculations, leaving countless beneficiaries with limited or no access to medically necessary services when they are needed.

MAO reliance on narrow networks increases beneficiary out-of-pockets costs by forcing them to seek medically necessary care "out-of-network." This runs counter to federal efforts to ensure access to the right care, at the right time, from the most appropriate provider. As described above, there are limited federal standards in place for MAOs, but these are insufficient to protect patients from unduly narrow networks.

Narrow networks are also a significant issue in "Marketplace" plans; however, we recognize that discussion of non-Medicare issues is outside the scope of the Committee's request. The Alliance would appreciate the opportunity to discuss network adequacy in the broader context at a future time.

Related Statute/Regulation:

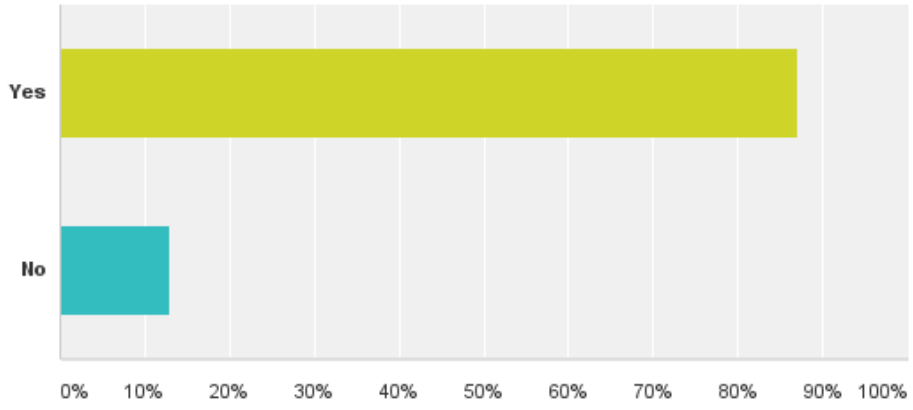
Market Stabilization Final Rule: 82 FR 18346-18382; 45 CFR 156.230
Medicare Advantage Network Access and Availability Standards: 42 CFR 422.112

Proposed Solution:

The Alliance asks Congress to enact legislation that would establish network adequacy standards for federally-regulated health care plans that ensure beneficiaries can access the most appropriate providers, including specialty and subspecialty physicians, for their health care needs.

At the end of 2016, in anticipation of healthcare discussions, the Alliance of Specialty Medicine began work on a survey of 1,000 of its provider members to quantify some of the issues that specialty physicians are facing in insurance markets. Highlights are below.

Have you delayed or avoided prescribing a treatment due to the prior authorization process associated with it?

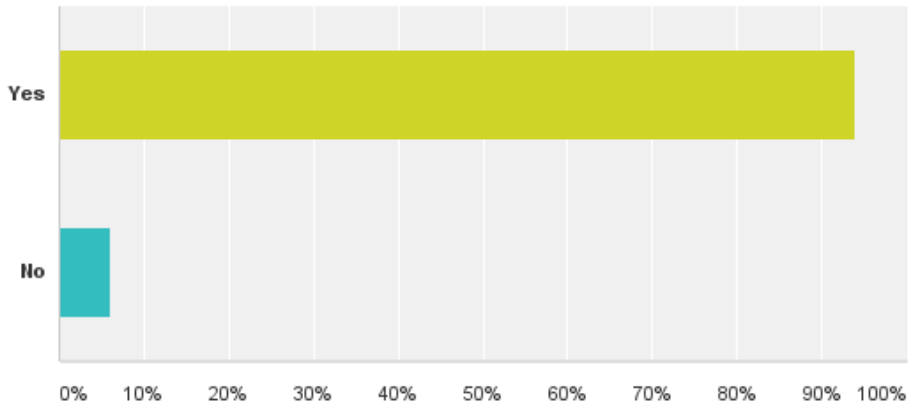


"I have patients that have been hospitalized and almost died due to the delays imposed by prior authorizations and inexperienced unknowledgeable "physicians" […] making decisions on complex rheumatologic treatments being given to seriously ill rheumatology patients - this is shameful, if not criminal."

"Never have I spent more time on administrative issues that do nothing but delay appropriate diagnostic and therapeutic intervention."

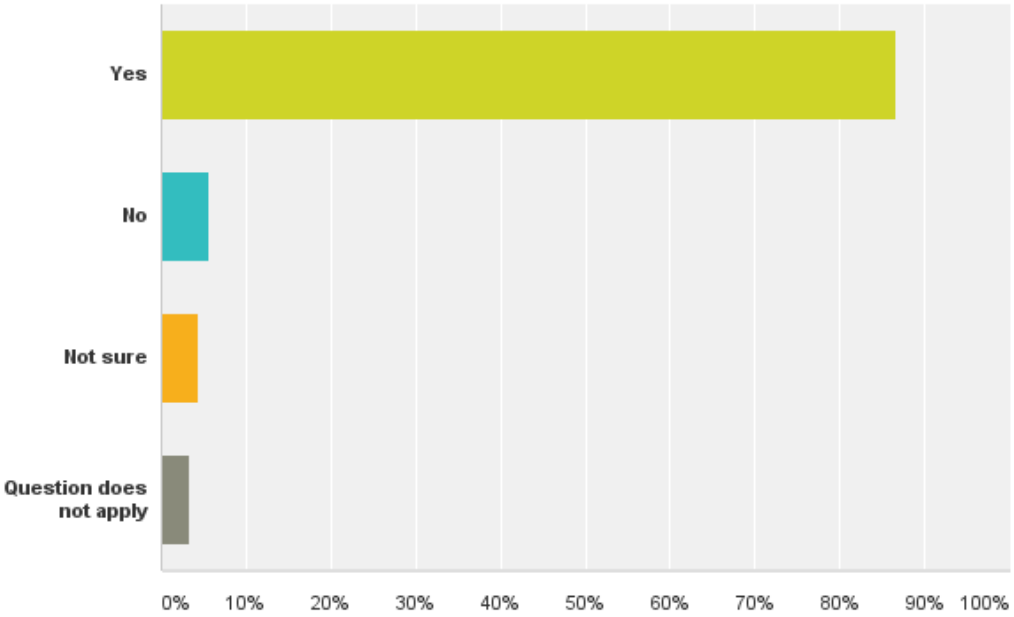
"Patient with spinal tumor and cord compression was denied [for surgery], because we did not try Physical Therapy."

Have increased administrative burdens by insurers influenced your ability to practice medicine?



"I practice neurosurgery at a Level 1 Trauma and Comprehensive Stroke Center. It is common for some insurers to refuse to pay for emergency care without prior authorization, even when it was a matter of life or death (accident, gunshot wound, hemorrhagic stroke, hydrocephalus, etc.)."

In the past five years, have you experienced an occasion during which a stable patient was asked to switch from his/her medication by the insurer even though there was no medical reason to do so?



"This happens ALL THE TIME. It is not "asking" to switch, it is "forcing" when they charge patients exorbitant costs to continue their medication."

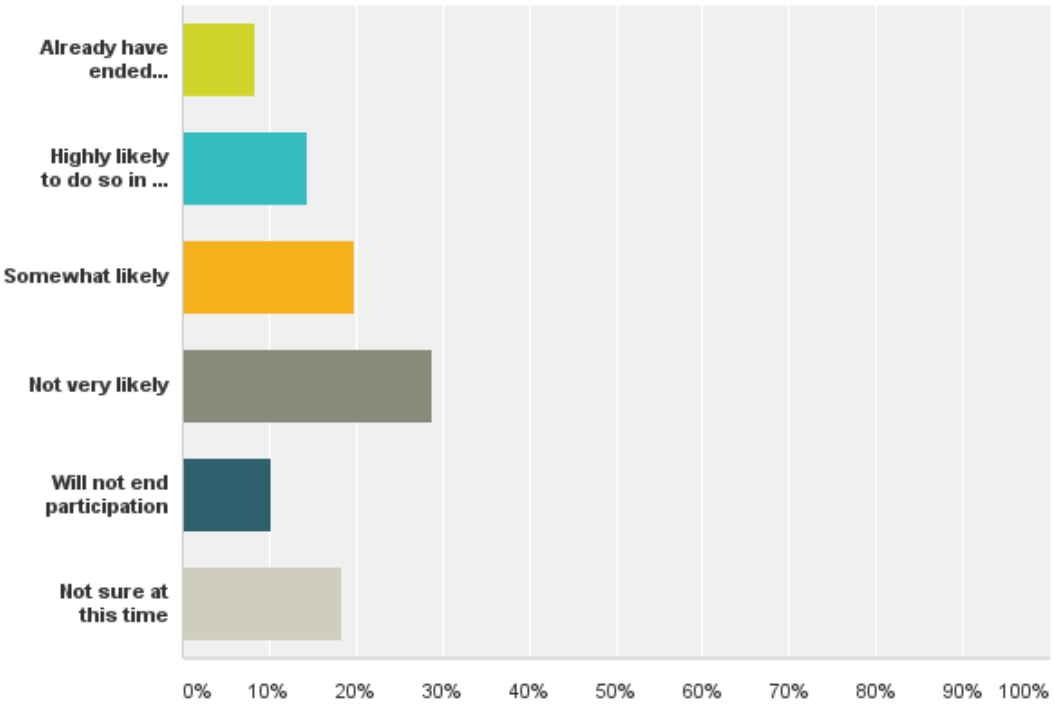
"It feels like insurers are practicing medicine without a license."

How likely are you to end your participation with any insurers due to the issues discussed in this survey?

"I take all insurances basically to improve access of care [in] my area even at personal losses. I am not sure how much longer we can do this."

"I miss actually taking care of patients."

"I treat patients not insurers. Ending participation just restricts patients."



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Short Description: Medicare Advantage and Part D Prior Authorization

Summary:

Prior authorization (PA) under Medicare Advantage (MA) and Part D creates burden on clinicians and limits patients' ability to access the care and medications recommended by their physicians. A survey completed by over 1,000 clinicians represented by Alliance member organizations (see Appendix A: Alliance Survey Highlights) illustrates the burden imposed by prior authorization and related plan administrative requirements on practices and patients.

Such burden is compounded by the use of multiple different prior authorization request forms used by plans across both programs, as well as by many plans' failure to operate prior authorization processes using electronic transactions such as the HIPAA-mandated transaction for medical services PAs (X12 278) and the National Council for Prescription Drug Programs' (NCPDP) standard electronic transactions for pharmacy PAs.

Related Statute/Regulation:

No requirements exist at the following locations:
Medicare Advantage: 42 CFR 422; Medicare Managed Care Manual Chapter 13
Part D: 42 CFR 423, Medicare Prescription Drug Benefit Manual Chapter 6 or Chapter 9

Proposed Solution:

The Alliance asks Congress to work with CMS to streamline the prior authorization process used by Medicare Advantage and Part D plans by requiring standardized forms and electronic transactions; such requirements do not currently exist. We encourage sparing use of prior authorization to ensure timely delivery of standard, evidence-based treatment for given conditions and not based solely on cost criteria. We also encourage processes that allow for true "peer-to-peer" dialogues. Specialists seeking prior authorization for pharmaceutical therapy or advanced diagnostic imaging on behalf of a patient should be routed to a specialist in the same or similar discipline with expertise in the patients diagnosis to discuss the request – not a pharmacist, nurse, other allied health professional, or physician unfamiliar with the disease processes and care management protocols associated with the given condition. Congress might also consider expanding the Recovery Audit Contractor (RAC) Program program to include MA prior authorization practices. Where MA plans consistently fail RAC audits, corrective action plans may be imposed, which, if not remedied, may include termination of the plan.

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Medicare Red Tape Relief Project

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Address for Submitting Organization:	3823 Fordham Rd NW, Washington, DC 20016
Name of Submitting Staff:	Vicki Hart
Submitting Staff Phone	(202) 729-9979
Submitting Staff E-mail:	info@specialtydocs.org

Statutory___ Regulatory_X__

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Short Description:	Centers for Medicare and Medicaid Services (CMS) Program Integrity Initiatives

Summary:

The Alliance of Specialty Medicine is increasingly concerned with CMS' approach to program integrity, which places numerous, burdensome requirements on physician practices. These initiatives are duplicative and disruptive to physician practices; for example, CMS and its contractors conduct multiple types of pre-payment review, post-payment review, and medical record auditing to determine the accuracy of federal payments, with different contractors often requesting the same medical records. CMS also provides little transparency with respect to the scope, authority, and operations of initiatives they undertake, thereby creating additional uncertainty for the physician community and limiting accountability for CMS and its contractors. CMS' program integrity efforts also often lead to penalties based on technicalities or inconsistent application of program requirements (e.g. with respect to local coverage determinations). Further, they do not include sufficient safeguards to ensure that contractors make appropriate determinations with respect to denial of claims or services or identification of overpayments. In addition, penalties are often incommensurate with the identified errors, particularly given that improper payments are largely due to unintended coding and billing errors of providers acting in good faith, rather than bad actors committing fraud.

Related Statute/Regulation:

Assorted, including: 42 CFR 421; 42 CFR 402; 42 CFR 420; Medicare Program Integrity Manual

Proposed Solution:

To address the above concerns, the Alliance urges Congress work with CMS to:

- **Streamline Medicare program integrity efforts to minimize burden and duplication.** CMS should identify opportunities to consolidate the function and scope of the various Medicare program integrity auditors, reducing the complexity of program integrity initiatives and ultimately the volume of audits on providers.
- **Increase transparency in Medicare medical review and audit initiatives.** CMS should establish a new web portal for consolidating information on program integrity efforts and information/education on its various program integrity contractors, including contractor sampling and extrapolation methodologies. CMS should annually publish key data related to various audits, including the number of denials and appeals, net denials (defined as total denials minus denials overturned on appeal) and each auditor's appeal rate. Medicare auditors should also be required to submit potential audits for review and approval by the Secretary, and approved audits should be made public.
- **Enforce transparency in the development of local coverage and payment policies**, by requiring contractors to adhere to CMS' established requirements for soliciting comments and recommendations, and for obtaining input from representatives of relevant specialty societies, as part of the contractor's notice and comment period for new or revised local coverage determinations (LCDs). Local contractors must also be required to provide a formal notice and comment process for any and all changes they intend to implement that would revise coverage and payment policies.
- **Implement safeguards to ensure that Medicare denials and overpayment recoupments are proper**, by requiring a physician practicing in the same specialty or sub-specialty and with clinical expertise or knowledge of the service in question, to validate whether a medical necessity denial is warranted. In addition, Medicare auditors should face a financial penalty when their denials are overturned on appeal in order to strengthen incentives to make correct determinations from the start.
- **Promote improvement through education and corrective action plans (CAPs) rather than penalties**. CMS should publicly report common coding and billing errors and omissions using various metrics (e.g., error type, omission type, physician specialty, contractor, and region, among others). CMS should also enhance educational offerings to physician practices on how to avoid common coding and billing mistakes, particularly as medical professionals are continuing to learn the ICD-10 coding system which was only recently implemented. In addition, CMS should also replace financial penalties with corrective action plans (CAPs) that provide clear steps for physician practices to reduce their improper payment rates. CMS should also institute a program that would provide technical assistance to physician

practices while they work to address internal deficiencies that may have led to a high volume of coding and billing errors and inappropriate payments that have not been deemed fraudulent.

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Statutory_X__ Regulatory_X_

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Short Description: Sunset Quality Programs for Physicians and Other Eligible Professionals

Summary:

Under current law, physicians and other eligible professionals are subject to requirements and related penalties under three programs:

- Electronic Health Records (EHR) Incentive Program: Section 1848(a)(7) of the Social Security Act provides for payment penalties of 3 percent for every claim submitted by certain eligible professionals for 2018 who have not demonstrated meaningful use of certified EHR technology (or CEHRT) in accordance with program rules.
- Physician Quality Reporting System (PQRS): Section 1848(a)(8) of the Social Security Act provides for payment penalties of 2 percent for every claim submitted by certain eligible professionals for 2018 who have not satisfactorily submitted data on quality measures in accordance with program rules.
- Value-Based Payment Modifier (VM): Under Section 1848(p), CMS has the authority to apply differential fee schedule payment adjustments to a physician or a group of physicians based on their quality and cost performance. CMS has the flexibility to determine the extent of these adjustments so long as they are applied in a budget neutral manner. For 2018, the program includes potential downward adjustments of up to 4 percent for every claim submitted by certain eligible professionals (or groups) who demonstrate low quality and/or high cost performance in accordance with program rules. The total amount of downward adjustments will determine the extent of upward adjustments, which will apply to every claim submitted by certain eligible professionals (or groups) for 2018 who demonstrates either average cost/high quality; low cost/average quality; or low cost/high quality, all in accordance with program rules.

These programs are set to expire at the end of 2018 under provisions in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which is intended to streamline burdensome and overlapping requirements for physicians under these programs. At the same time, MACRA established a new framework for assessing clinicians and adjusting payments based on their performance across four performance categories called the Merit-Based Incentive Payment System, or MIPS.

Physicians will need to invest time and resources as they transition to the new regulatory regime established under MACRA, which necessitates relief from penalties. Providing penalty relief for these three pre-MACRA legacy programs will also enable clinicians to better prepare for MACRA's Quality Payment Program (QPP). At the same time, the opportunity for upward adjustments should not be eliminated for those clinicians or groups who already invested resources and succeeded at demonstrating high performance under the VM.

Related Statute/Regulation:

Electronic Health Records (EHR) Incentive Program: Social Security Act Section 1848(a)(7); 42 CFR 495.102
Physician Quality Reporting System: Social Security Act Section 1848(a)(8); 42 CFR 414.90
Value-Based Payment Modifier: Social Security Act Section 1848(p); 42 CFR 414 Subpart N (414.1200-1285)

Proposed Solution:

The Alliance asks Congress to consider either a regulatory or statutory solution that would provide relief from penalties facing physicians in 2018 based on reporting and performance under the EHR Incentive Program, PQRS, and the VM programs. CMS, in its calendar year (CY) 2018 Physician Fee Schedule proposed rule included changes that, if finalized, would lower the reporting requirements for avoiding the 2018 PQRS and EHR Incentive Program penalties and reduce the magnitude of applicable Value Modifier penalties if they are triggered. However, we believe that all clinicians who at least attempted to report any data during the last years of these programs should be provided full relief from penalties under each of these three programs. Applying penalties only to clinicians who did not attempt to report anything will ensure that CMS still has a pool of funding available to reward high performers with upward payment adjustments under the VM. This could be accomplished via regulation if CMS finalizes such policies in the CY 2018 Physician Fee Schedule final rule. Absent such action, statutory changes would be required.

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Short Description:	Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Certified Electronic Health Record Technology (CEHRT) Policies

Summary:

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-Based Incentive Payment System (MIPS) to assess clinician performance across four categories: quality, resource use, use of certified electronic health records, and adoption of clinical practice improvement activities. Based on performance across these four categories relative to a "performance threshold," clinicians may receive upward or downward adjustments to their Medicare payments starting in 2019.

In final regulations released October 2016 that specified initial requirements for use of certified electronic health record technology (CEHRT) under MIPS, CMS required that clinicians would have to adopt 2015 Edition CEHRT by the 2018 performance period and report measures comparable to Stage 3 Meaningful Use. This requirement is overly burdensome and unrealistic. Clinicians are still adjusting to Modified Stage 2 measures, which were only finalized in October 2015, while also transitioning to the new Quality Payment Program. Further, availability of 2015 Edition CEHRT for clinicians is extremely limited, particularly for specialists who have few relevant EHR options that respond to their individual practices' needs. Finally, and perhaps most importantly, Stage 3-like measures necessitate more robust interoperability and seamless data exchange between disparate systems, which is not available at this time. Requiring clinicians to adopt 2015 Edition CEHRT and report more aggressive measures only sets them up for failure.

CMS proposes to rescind the requirement to adopt and use 2015 Edition CEHRT for 2018 in the calendar year 2018 updates to the MIPS that CMS released this past June. However, there is no guarantee that, even if finalized, CMS would maintain this policy in future years.

Furthermore, we continue to have concerns about the MIPS requirement that clinicians, at the very least, satisfy the base measure reporting requirements in order to receive a score in the Advancing Care Information category. This strategy is really no different than the all-or-nothing approach that CMS claims to have moved away from. We oppose the fact that metrics under this category, which are borrowed from Stage 2 and 3 of the legacy program, continue to focus more on EHR functionality than providing physicians with the flexibility to demonstrate meaningful use in a manner that is most relevant to their practices.

Related Statute/Regulation:

Definition of CEHRT for MIPS: 42 CFR 414.1305
MIPS Final Rule (starting with calendar year 2017): 81 FR 77008-77831
Calendar Year 2018 Updates to MIPS (Proposed Rule): 82 FR 33950-34203

Proposed Solution:

To address these challenges and facilitate more thoughtful and measured adoption of CEHRT and requisite measures, Congress should ensure that CMS delays the requirement to adopt 2015 Edition CERHT and require measures comparable to Stage 3 Meaningful Use under MIPS indefinitely. At a minimum, 2015 Edition CEHRT should not be required until such time that robust interoperability has been broadly established, and data exchange is seamless across the health care system.

We also continue to urge CMS to offer clinicians the broadest selection of measures to choose from for purposes of the Advancing Care Information category and to not require the use of any single measure to receive a score in this category.

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Short Description:	Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Virtual Group Policies

Summary:

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Merit-Based Incentive Payment System (MIPS) to assess clinician performance across four categories: quality, resource use, use of certified electronic health records, and adoption of clinical practice improvement activities. Based on performance across these four categories relative to a "performance threshold," clinicians may receive upward or downward adjustments to their Medicare payments starting in 2019.

MACRA established the availability of "virtual groups" for eligible clinicians in group practices of 10 or fewer clinicians to voluntarily elect to partner with other clinicians or group practices for the purposes of collective assessment under the MIPS program. Per statute, these virtual groups could be based on "appropriate classifications of providers, such as by geographic areas or by provider specialties." However, MACRA also specified that virtual groups must be a combination of tax identification numbers (TINs), which prevents specialty groups that participate in the Medicare program as part of larger TINs to take advantage of virtual groups. This creates a barrier for such specialty groups to partner with other similar specialists to be assessed as a virtual group on measures and activities that are most meaningful for the specialty. Additionally, MACRA generally identifies small practices as those with 15 or fewer eligible clinicians. The cutoff of 10 or fewer eligible clinicians required to participate in a virtual group is an anomaly that does not recognize the challenges that practices with 11 to 15 clinicians share with smaller practices regarding infrastructure investments, training, burden, and more. Further, it is not clear that an arbitrary limit to participation in virtual groups is appropriate at all; to the extent that groups of eligible clinicians all agree that it is in their interest to form a virtual group in order to be meaningfully assessed on their performance, it may be appropriate to lift the size restriction altogether.

Related Statute/Regulation:

Resource use category weight: Social Security Act 1848(q)(5)(E)
Performance Threshold: Social Security Act 1848(q)(6)(D)(i)

Proposed Solution:

To increase the availability of virtual groups, the Alliance asks Congress to (1) remove the requirement that virtual groups must be a combination of TINs in order to allow subgroups within a TIN to potentially align virtually; and (2) increase eligibility for participation in virtual groups to include larger groups; at a minimum, groups with 15 or fewer eligible clinicians should be allowed to participate in virtual groups.