

AAHKS Regulatory Burdens Recommendations

Name	Burden	Source of Burden (statutory or regulation reference)	Recommendation	Commentary
AAHKS	Inadequate Risk Adjustment in Alternative Payment Models: Lack of risk adjustment creates a disincentive for physicians to treat medically complex patients (e.g. CJR). This is a fundamental threat to the physician-patient relationship that must be addressed for APMs to succeed.	Regulatory: 42 CFR 510 (CJR Model)	<p>We recommend the CMS Innovation Center to work with relevant specialties and associations to create appropriate risk adjustment/stratification methodology to accommodate medically complex patients.</p> <p>This consultation should be required for all new APMs and addressing existing APMs with inadequate risk adjustment should be a CMMI priority. At minimum, the risk adjustment model used in the Yale/CMS Risk Standardized 90 Day Episode Cost Measure for Total Hip and/or Total Knee replacement should be implemented in CJR and future AAPMs.</p>	
AAHKS	Lack of Physician Control in Bundled Payment Models: The CJR Model lacks physician control of the bundle.	Regulatory: 42 CFR 510 (CJR Model)	We recommend the establishment of flexibility in bundled payment programs (e.g. CJR) to allow physicians to control the bundle and share risk if they so choose. Evolving concepts like the BPCI Facilitator Convener is also a positive step.	The physician has the most contact with the patient, and the most influence on clinical outcomes. Under a bundled payment model, it is imperative that the physician lead the effort to ensure the patient is receiving the right care, at the right time, in the right setting in order to meet bundled payment benchmarks.

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AAHKS	Regional/Geographic-Based Episode Target Prices in Bundled Payment Programs: Regional pricing targets provide a disincentive for physicians to treat medically complex patients. Practices that deliver care to high acuity/medically complex patients should not have the same target prices as a practice that provides care to lower acuity/low-risk patients. Similar to risk adjustment considerations, this issue fundamentally impacts the physician-patient relationship.	Regulatory: 42 CFR 510 (CJR Model)	We recommend maintaining the 2/3 historical episode blend as described in 42 CFR 510.300(b)(2)(i) for all performance years as an immediate step, and then allow for the development of risk adjustment methodology to appropriately account for medically complex patients.	CJR's episode target prices begin as a blend of 2/3 facility history & 1/3 regional pricing. Eventually the blend shifts to a 100% regional price target, exacerbating inequities between practices based on the acuity & medically complexity of their patient population.
AAHKS	Restrictive CJR Participation Criteria: There are practices that are interested in participating in the CJR model, but are not located in one of the participating MSAs.	Regulatory: 42 CFR 510 (CJR Model)	We recommend opening up the participation criteria under the CJR regulations to permit broader voluntary participation in CJR.	Permitting physicians interested in participating in CJR to do so will allow more practices to test the model, and provide offsetting participation for removing mandatory participation requirements.
AAHKS	Mandatory APM Demonstrations: APM Demonstrations should not be mandatory.	Regulatory: 42 CFR 510 (CJR Model) Regulatory: 42 CFR 1315a (CMMI)	We recommend promulgating regulations that prohibit CMMI from establishing mandatory demonstration programs. The CJR model should be changed to a voluntary model.	
AAHKS	Medicare Signature Requirements: Medicare mandates that the practitioner must sign and document directly in order to submit a claim for medical services and supplies.	Subregulatory - Medicare Program Integrity Manual, (Publication [Pub.] 100-08), Chapter 3, Section 3.3.2.4.	We recommend amending Medicare requirements to allow a surgeon to supervise a team that collectively documents and signs for them.	Medicare requirements for physicians to be directly involved with administrative tasks reduces time they should be spending with their patients.

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AAHKS	Medicare Home Health Face-to-Face (F2F) Encounter Requirement: Requires a physician/practitioner to have a face to face consultation with the patient about the services involved.	Regulatory: 42 CFR 424.22(a)(1) Statutory: PPACA Section 6407(a)	We recommend suspending enforcement (MAC, CERT etc) of the F2F policy.	Requirement for patients to have face to face time for home health should be removed via legislation.
AAHKS	Medicare DME Face-to-face (F2F) Encounter Requirement: Requires a physician/practitioner to have a face to face consultation with the patient about the supplies involved.	Regulatory: 42 CFR 410.38 Statutory: PPACA Sec. 6407 (b)	We recommend suspending enforcement (MAC, CERT etc) of the F2F policy.	Requirement for patients to have face to face time for certain DME should be removed via legislation.
AAHKS	Meaningful Use Incentive Program: Stage 3 Meaningful Use criteria are overly burdensome on physicians and other providers.	Regulatory: 42 CFR 495	We recommend using Stage 2 Meaningful Use criteria for all relevant federal programs.	Stage 3 meaningful use is too burdensome for most providers. Small practices already struggle to dedicate resources to MU compliance, however Stage 3 requirements are unattainable for even the most sophisticated and resourced health systems.
AAHKS	Inflexible Medicare Medical Necessity Requirements and Documentation: The Medicare requirements to satisfy medical necessity for TJA is incompatible with some patient cases, and can delay necessary care.	Subregulatory - MAC LCDs	We recommend providing for consultations with the appropriate specialty organizations to establish criteria for medical necessity, including providing flexibility for cases where 3 months of conservative treatment is not an appropriate pre-requisite for coverage.	Current medical necessity requirements demand that 3 months of conservative treatment be attempted and failed. A physician can determine in some of these cases, that 3 months of conservative treatment will 1) be ineffective, 2) put the patient through undue suffering, 3) delay patient care, and 4) waste medical resources.
AAHKS	Three-Day Inpatient Hospital Stay Requirement for Care in a Skilled Nursing Facility: Limits patient ability to access rehabilitative services.	Regulatory: 42 CFR 409.30(a) Statutory: 42 U.S.C. 426(c)	We recommend eliminating the requirement.	APMs like CJR and Medicare Next Gen ACO provides for a waiver of the 3 Day requirement; displaying that the policy is not necessarily in the patient's interest.
AAHKS	Discharge Planning: Limits physician ability to manage quality of care throughout an episode.	Regulatory: 42 CFR 482.43	We recommend providing the ability for physicians to make recommendations to their patients regarding post-acute providers.	Physicians know which post-acute providers from which their patients receive the best outcomes. They should be allowed to impart that knowledge to help their patient navigate their rehabilitation.

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AAHKS	<p>Stark, Anti-kickback, Civil Monetary Penalty and 503C Laws: They are impeding care coordination, the transition to value based care and are disproportionately punitive for technical violations.</p>	<p>Regulatory: Multiple Statutory: Multiple</p>	<p>We recommend engaging stakeholders in a Stark, Antikickback, Civil Monetary Penalty and 503c law review to clarify safe harbors and exemptions.</p>	
AAHKS	<p>Medicare Advantage and Managed Medicaid Prior Authorization Programs: Prior Authorization programs, including peer-to-peer reviews, are an additional burden on physicians.</p>	<p>Subregulatory: Medicare Advantage Plans, Managed Medicaid Contractors Regulatory: 42 CFR Part 422</p>	<p>We recommend focusing prior authorization programs on physicians who have high denial rates, and exempt the majority of responsible physicians.</p>	<p>Often the peer-to-peer consultation results in overturning the original denial. Peer-to-peer consultations are not always done by a physician in a relevant specialty.</p>
AAHKS	<p>Quality Reporting Requirements: physicians find no value to the quality reporting to medicare—this should be outsourced to AJRR and AAHKS to certify that surgeons are reporting to the registry and CMS can fund a more robust AJRR</p>	<p>Regulatory: 42 CFR 414.90</p>	<p>We recommend developing an option the provides the ability to outsource Medicare quality reporting requirements to registries (AJRR) and associations (AAHKS) to certify that surgeons are reporting meaningful data</p>	
AAHKS	<p>Burdensome Pathway for Quality Measure Development: The difficulty of getting quality measures through the NQF process has contributed to the dearth of specialty quality measures.</p>	<p>Subregulatory: CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) Regulatory: 42 CFR 414.90 (PQRS) Statutory: 42 USC 299b–31 (AHRQ-NQF) Statutory: 42 U.S. Code § 1395w–4 (q)(2) (MIPS) Statutory: 42 U.S. Code § 1395w–4 (s)(Measure development plan)</p>	<p>We recommend seeking a direct pathway for approving specialty society endorsed measures for reporting and incentive programs.</p>	

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AAHKS	Lack of A-APM Opportunities: The MIPS track of the Medicare Quality Payment Program is not attractive to many of our Members, and there is a need for multiple APMs that qualify for the A-APM track.	Regulatory: 42 CFR 414 Subpart O	Create more direct pathways for submitting potential AAPMs reserving the PTAC step for questionable offerings.	The establishment of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) is a step in the right direction. We are hopeful that the PTAC serves as a clearinghouse and not a bottleneck.
AAHKS	Threshold for A-APM Track Eligibility: One of the thresholds for qualifying for the A-APM track for 2021 and beyond is that the physician have 75% of Medicare payments through an A-APM. This is an unrealistic threshold for broad A-APM participation.	Regulatory: 42 CFR 414 Subpart O	We recommend lowering the A-APM track eligibility threshold for % of payments required to be billed through an A-APM in 2021 and beyond.	
AAHKS	Lack of Risk Stratification in MIPS: Physicians who participate in MIPS should be evaluated based on the risk and acuity characteristics of their patient population.	Regulatory: 42 CFR 414 Subpart O	We recommend engaging specialty societies and stakeholders to develop MIPS risk adjustment criteria.	MIPS is at risk of encountering the same risk adjustment deficiencies as APMs; impacting the patient-physician relationship.
AAHKS	Bundled Payment Models should not be a zero-sum game: (e.g. BPCI Reimbursement model)	Regulatory: 42 CFR 510 (CJR Model) Regulatory: 42 CFR 1395cc-4 (BPCI Model)	We recommend adjusting the incentives in bundled payment models to allow for the possibility of success and reward for improving quality and lowering costs in the majority of hospitals without forcing inter-hospital gaming and patient exclusion.	
AAHKS	Inadequate Coding System: Coding systems have not kept pace with technology and procedures. Coding deficiencies have led to inarticulate datasets, limiting potential benefits of data analysis.	Regulatory: Annual Payment Rules	We recommend establishing more detailed CPT and ICD10 codes to better capture modern TJA practices and procedures.	