



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

December 9, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: Request for Information on the Future of Program Integrity

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the request for information on the future of Centers for Medicare & Medicaid Services' (CMS) program integrity efforts.

CHA looks forward to working with the agency to further define future programming integrity efforts. More specifically, CHA urges CMS to first prioritize provider and contractor education, promoting shared understanding of expectations across all entities. When guidance is clear and well understood, and appropriate oversight is in place to limit variation in contractor implementation, we avoid duplicative and costly audits that not only confuse patients and providers, but also add significant costs to the health care system. We encourage CMS to pursue program integrity efforts that are integrated and fully aligned with provider compliance and education. Far too often, providers find themselves caught in the middle of complex and unclear regulatory guidance, which leads to differing interpretations and application of CMS policy across contractors and other agencies. We hope that, through this effort, CMS and its contractors will work with stakeholders — including other agencies when appropriate — to build an infrastructure that more fully integrates, where appropriate, these functions across the agency.

Program Integrity for Value-Based Payment Programs

Before adopting more focused program integrity efforts across CMS value-based models, we believe more can — and should — be done to streamline the regulatory frameworks and inconsistent guidance many providers encounter as they engage with CMS in both voluntary and mandatory alternative payment models. There are tremendous opportunities to build on existing experience in commercial markets, where the regulatory frameworks are far less restrictive and not based on a fee-for-service infrastructure. Value-based payment (VBP) programs include risk-based, capitated arrangements, among others, that promote a delivery system focused on value over volume. However, current CMS regulatory frameworks have not kept pace with the changing market. To fully align risk, CMS must take additional action to remove barriers that continue to misalign the incentives for sharing risk. In doing so, CMS will be will have a more informed program integrity strategy.

Key to such evaluation, prior to rollout of a strategy, are data. As with any VBP program, when reimbursement shifts from a fee-for-service, claims-based system to risk-based reimbursement (based on episodes, bundles, capitation, etc.), CMS must continue to focus on the quality of care provided to

beneficiaries. Equally as important are the quantity and quality of the data provided to the agency for evaluation of that care. Creating a data strategy that promotes program education and compliance while helping to identify fraud, waste, and abuse is key. Without quality data (from both Medicare and Medicaid), it is very difficult — if not impossible — to assess the delivery system and determine anomalies that require agency action.

California's Medicaid and Medicare Advantage (MA) markets rely significantly on the delegated or sub-capitated arrangements. For example, United Health Care may delegate full risk to a large physician group, making the physician group — not the health plan — the responsible entity. The physician group is responsible for administration, including prior authorization, utilization review, and payment of claims for all services. These arrangements are not necessarily transparent to other providers or to beneficiaries, which limits full transparency into the processes as well as the network and creates significant challenges for oversight and accountability. Further, once risk is delegated, encounter data are not typically shared with the health plan.

With these arrangements prevalent in the California market, the state has significant challenges in receiving accurate and timely encounter data for evaluation and oversight. Under these circumstances, there are inherent risks CMS should further explore as it considers new strategies. CMS could consider greater contractual oversight of the primary contracted health plans (in Medicaid and Medicare) and their delegated entities or sub-capitated partners. This should include greater visibility into their networks through improved reporting requirements for plans that choose to enter into these arrangements and implementation of penalties for the primary contracted health plan when delegates are non-compliant with contract provisions.

California's recent experience with the CMS Duals Demonstration pilot in eight counties across the state also presented its fair share of challenges for both providers and oversight agencies. While the data sharing was helpful — likely because it was incentivized in the model's framework — California's hospitals encountered several challenges ensuring plan compliance with various CMS and state policies. This was further complicated in the delegation of risk from the health plan to large medical groups. Transparency of networks and consistent policy application remain a challenge in these complex arrangements.

In addition, certain health plan utilization management techniques jeopardize patients' access to care while increasing burden and costs in the health care system. Particularly problematic are systematic and inappropriate delays of prior authorization decisions, payment denials for medically necessary care, failures to maintain adequate provider networks, and unilateral changes in the rules for both patients and providers. These actions contribute to hundreds of billions of wasted dollars each year¹, and put patients at risk of not being able to access the care they need or the coverage to which they are entitled.

We remain very concerned the agency will look to the commercial market to inform its program integrity efforts. CHA urges CMS to do more to limit this type of behavior by contracted health plans — this should be the starting point for any improved program integrity strategy.

¹ Shrank, W. et al., "Waste in the US Health Care System: Estimated Costs and Potential for Savings," JAMA: The Journal of the American Medical Association. October 7, 2019.

Finally, development and implementation of a data strategy that aligns with provider education will help to differentiate between providers coming up to speed on new policies and appropriate identification of fraud, waste, and abuse. It is very difficult — if not impossible — to assess the delivery system and determine anomalies that require agency action in the absence of such alignment.

Prior Authorization for Fee-for-Service

Prior authorization is a tool that, when used appropriately, can help align patients' care with their health plan benefit structure and facilitate compliance with clinical best practices. However, prior authorization requirements and processes vary widely, even among different health plan products offered by the same issuer, and can create dangerous delays in care delivery when not applied appropriately. They also can create confusion and burden for both patients and providers, increasing administrative costs for the health care system.

Often, the use of prior authorization is questionable altogether, as when health plans require authorization for services when there is no evidence of abuse and for which the standards of care are well-established. Unfortunately, CMS is moving forward in implementing a prior authorization process as outlined in the calendar year (CY) 2020 outpatient prospective payment system (OPPS) final rule.

In an effort to control for what CMS deems “unnecessary increases in the volume of certain covered outpatient services,” CMS will implement a prior authorization requirement for several categories of services, including blepharoplasty, botulinum toxin injections, panniculectomy rhinoplasty, and vein ablation effective July 1, 2020.

CHA remains extremely concerned with CMS' assertion — which lacks clear and convincing evidence — of “unnecessary increases in volume of services for certain covered outpatient services.” We urge the agency to revisit its analysis of the claims data and present additional evidence — beyond increases above the national average — of over-utilization. Such a narrow view is contrary to the agency's responsibility to ensure beneficiaries have access to high-quality health care services. Absent a robust analytical framework, including input from clinical experts and medical record reviews from which to assess unnecessary increases in the volume of services, the agency has provided no convincing evidence to support such a significant change in fee-for-service policy. With such limited data to support its findings, CMS could overlook other causes for increases in utilization — for instance, the Food and Drug Administration approved the use of Botox for treatment of migraine headaches in 2010, which could explain recent increases in Botox injections.

This policy, as outlined in the final rule, presents significant challenges and a number of questions remain unaddressed. Patients consult with their doctors in determining their course of treatment. Continuing to put hospital administrators in the middle of that patient-clinician relationship under a prior authorization process is ill-advised. Unlike most states, the vast majority of hospitals in California are unable to employ their doctors and, as such, must navigate a complex regulatory framework to fully integrate. Policies like these, when applied to a hospital outpatient department setting but not the physician office setting, create misalignment, clinician frustration, and beneficiary confusion.

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services published in September 2018 a report titled *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Services and Payment Denials*. The report noted:

- CMS audits found widespread and persistent problems related to denials of care and payment in MA, including insufficient denial letters, inappropriate denials related to insufficient outreach, and inappropriate denials related to incorrect clinical decisions. More than half of the MA contracts were cited for inappropriate denials.
- Incorrect or incomplete denial letters (seen in half of the audited MA organization contracts) may inhibit beneficiaries' and providers' ability to appeal.
- When MA beneficiaries and providers appealed, they were usually successful in getting denials overturned. Overturn rates at the initial (plan) level ranged from 0 to 100%, with a median of 77%.
- MA beneficiaries and providers rarely used the appeals process. The OIG notes that contract-specific rates of appeal varied widely.

Based on its findings, OIG recommended that CMS enhance oversight of MA contracts, including those with high overturn rates and/or low appeal rates; address persistent problems related to inappropriate denials and insufficient denial letters; and provide beneficiaries with clear, easily accessible information about violations. We remain very concerned that these challenges will remain as CMS moves to adopt these policies in the fee-for-service payment system.

While CHA strongly opposes the implementation of a prior authorization policy in the CY 2020 OPPS for several reasons noted above, we are not opposed to additional discussion on the topic and are hopeful that CMS will consider stakeholder convenings in the future. The incentives of such a process in a fee-for-service payment system are — and should be — different than the flawed incentives inherent in a managed care environment. CMS proposes to model the prior authorization process after the durable medical equipment (DME) process that was initially outlined in statute. Such legislative authority does not currently exist in the OPPS system. Notably, the DME prior authorization program was up and running after a successful pilot and six years of agency engagement with Medicare administrative contractors (MACs) and suppliers *before* full implementation. Unfortunately, CMS does not intend to pilot this program in the outpatient fee-for-service setting. In addition, it is our understanding that when a new piece of DME equipment is added to the list for prior authorization, the process is rolled out on a limited basis and then scaled nationally. CHA remains very concerned that the agency underestimates the operational challenges this policy will create for hospitals. We encourage increased dialogue with stakeholders to limit any disruption in beneficiary access to medically necessary care, while limiting provider administrative burden.

We understand targeted probe and educate reviews, as well as post-payment reviews, have decreased substantially for DME that is subject to prior authorization. Conceptually, if a robust and meaningful prior authorization process was established for a limited number of services, there would be no need for pre- or post-payment reviews of those claims — including additional reviews by MACs and recovery audit contractors. Allowing for continued pre- and post-payment reviews of services subject to prior authorization under OPPS is the opposite of the agency's goal of reducing administrative burden; it will only add additional costs to already costly claims processing. We urge CMS to revisit this policy as it begins implementation.

CHA encourages CMS to begin the process of stakeholder engagement so that it may solicit additional input and lay a foundation for a meaningful dialogue about the opportunities and challenges a prior authorization process presents. We look forward to engaging in that dialogue.

Provider Education

As previously stated, CHA urges CMS to first prioritize provider and contractor education to promote shared understanding of expectations across all entities. When guidance is clear and well-understood, and appropriate oversight is in place to limit implementation variation among contractors, we can avoid duplicative and costly audits that only confuse patients and providers while adding significant costs to the health care system. CMS has recently made available to all providers, via a publicly accessible website, the CMS surveyor training for the Medicare Conditions of Participation (<https://surveyortraining.cms.hhs.gov/>.) CHA applauds the agency for taking this action and believes it is applicable across many aspects of the agency. For example, CMS provides education and written guidance to the MACs; there is value in making the same information more readily accessible to providers. We encourage CMS to continue to explore how it can approach program integrity efforts in a way that is integrated and fully aligned with provider compliance and education.

Another approach is to break down the agency silos that currently exist. Provider compliance teams are separate from program integrity teams, while the payment policy team is totally separate from the audit team — and contractors are managed by completely different parts of the agency. While this type of siloed approach may have served its purpose in a fee-for-service world, it is no longer as relevant as we move to value-based program design and shared risk. CHA encourages the agency to find additional opportunities for a matrix approach that allows for the appropriate integration and collaboration in a way that would strategically align the agency goals.

Finally, CHA and our member hospitals have actively engaged with our MAC on a variety of issues. We regularly convene and discuss the challenges in understanding, operationalizing, and implementing CMS guidance. All agree it's a worthwhile meeting and that our dialogues are productive. Unfortunately, there is no such forum for providers, CMS, and MACs to regularly meet with payment and policy staff on any number of these topics at the national level.

As a first step, we believe CMS should revisit the Medicare Technical Advisory Group (MTAG) process to help inform all aspects of provider education and compliance; this will, in turn, inform program integrity efforts. These MTAGs were not policy-setting bodies, but instead were groups of stakeholders and agency staff tasked with solving a specific set of problems. They have a proven track record of successful collaboration between agency staff and providers. The topic of improved provider education would be a great MTAG topic to assist the agency in reviewing and prioritizing of the request for information comments, as well as to assist with specific implementation recommendations. If CMS is unwilling to formalize its stakeholder process, we encourage you to conduct informal outreach on a regular basis with providers and associations including CHA.

CHA appreciates the opportunity for additional time to provide our comments on the request for information. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688; or my colleague Ryan Witz, vice president of health care financing initiatives, at rwitz@calhospital.org or (916) 552-7642.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs