

July 27, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules (CMS-2390-P)

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding managed care programs in the Medicaid Program (Proposed Rule). As the first proposed revisions to the Medicaid managed care program's regulations in more than 12 years, the Proposed Rule includes many important provisions, which, when finalized, will have significant and broad-reaching impacts on Medicaid enrollees and the physicians who provide their care.

Since the managed care regulations were first adopted in 2002, the Medicaid program has changed significantly with millions more Medicaid beneficiaries receiving their care through managed care. Medicaid serves as the largest government payer of health care, and approximately 74 percent of Medicaid enrollees received services through managed care plans as of July 1, 2011. Over the past four years, enrollment in Medicaid managed care plans has increased by 48 percent, with 46 million enrollees receiving care through these plans. The AMA applauds CMS for taking important steps through these regulations to modernize and strengthen the Medicaid managed program by aligning its rules and requirements with other major sources of coverage, such as qualified health plans operating in the Marketplaces and Medicare Advantage (MA) plans. The AMA generally supports alignment of rules across public and private plans as a way to reduce administrative burdens on medical practices, improve care provided to patients, and promote accountability by the plans.

Grievances and Appeals

In general, the AMA supports CMS' efforts to update the Medicaid managed care grievance and appeal regulations and believes that many of the proposed changes would be beneficial to Medicaid enrollees and their physicians. Thus, we urge CMS to retain the following proposed changes in the final rule:

- require Pre-paid Ambulatory Health Plans to have a grievance process;
- expand and clarify that “adverse benefit determinations” include not only actions to terminate or reduce services, but also decisions about medical necessity for, and appropriateness or effectiveness of, services and the setting in which health care is provided, thereby making these additional decisions subject to notice and hearing rights;
- limit plans to requiring one level of internal appeal before beneficiaries are allowed to request a state fair hearing;
- enable providers to appeal on behalf of beneficiaries without the need for written consent from enrollees, such as under MA plans;
- provide notice of adverse benefit determination, including the reason for the adverse determination, including the right of the enrollee to be provided (upon request and free of charge) reasonable access to and copies of all documents, records, and other information relevant to the enrollee’s claim for benefits, including medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits;
- require all states to offer a 60-day time period to request external review through a fair hearing (some states currently allow a far shorter time period); in addition, plans would have only 30 days to make a determination on the appeal, reduced from the current 45 days;
- clarify members’ right to their case files, medical records, and other documentation, such as the plan documents used to conduct coverage determinations; and
- require plans to continue services until a final appeal decision, and thus eliminate the link between continued services and an authorization period.

While we agree with the proposed additions to the definition of “adverse benefit determinations,” as noted above, we recommend that CMS consider adding the following to the definition: denial of choice of provider or out-of-plan service requests and determination of a cost sharing amount. In addition, CMS has requested comment on its proposal to require enrollees to exhaust the plan level appeal procedures before gaining access to the State fair hearing. We do not support this proposal and urge CMS to allow states to continue to have flexibility to decide whether to require their residents to exhaust the plan-level grievance and appeal system before requesting a state fair hearing. Plan-level review may not be the most impartial review and the strongest protection for enrollees may be to allow them direct access to the state fair hearing. In addition, while we appreciate that CMS is proposing to shorten the timeframe for expedited appeals from three working days to 72 hours, we believe that 72 hours is still too long a time period to wait for plans to make decisions about critical issues, and urge CMS to consider a standard of 24 hours.

Medical Loss Ratio

The AMA strongly supports the application of a minimum medical loss ratio (MLR) to Medicaid managed care plans. During the debate over the Patient Protection and Affordable Care Act (ACA) and subsequent regulatory implementation of MLR requirements for health insurance issuers in the private insurance market, the AMA repeatedly expressed support for establishing greater transparency in the health insurance market and worked closely with the National Association of Insurance Commissioners (NAIC) in their development of a strong MLR standard. Premium transparency and medical loss ratio information are very valuable for patients.

We applaud CMS for proposing to implement MLR calculation and reporting requirements for Medicaid managed care plans and a requirement for states to use MLRs to set actuarially sound rates. This policy will promote transparency and accountability with public dollars and will allow consumers and governments to evaluate whether or not Medicaid programs are buying value for enrollees. The proposed policy could also help to increase rates for managed care plans that are providing value and reduce payments to plans that are not. We agree that CMS has the legal authority to implement these MLR provisions, consistent with statutory requirements pursuant to the Social Security Act to efficiently administer the program and pay managed care plans actuarially sound rates that cover “reasonable, appropriate and attainable costs in providing covered services.” We also agree that a MLR would be a vital tool to further compliance with these statutory mandates.

The AMA supports CMS’ proposal to set a uniform minimum MLR of 85 percent for states choosing to impose an MLR requirement. However, as CMS itself acknowledges, Medicaid and CHIP are the only health benefit coverage programs in 2015 to not utilize a minimum MLR for managed care plans—although 28 of the 38 states utilizing Medicaid managed care entities already impose MLRs of at least 85 percent (according to the Kaiser Family Foundation). We believe that CMS should require all states to impose an MLR requirement of 85 percent, and we urge CMS to make the regulatory text clear in this regard at section 438.8(c). In addition, without an enforcement mechanism such as requiring managed care plans to remit a portion of their capitation payment if they do not comply with the MLR, the requirement will be ineffectual. Thus, we urge CMS to align the MLR requirements in Medicaid with those applied to marketplace and other group plans and require plans to remit payment to states for noncompliance with the MLR. This will give states the tools they need to effectively enforce an MLR requirement.

Regarding which activities and expenses should be attributed to the MLR numerator, and whether “health quality improvement activities” should include service coordination, case management, and other activities particular to the more complex populations served by managed Medicaid care plans, the AMA believes that there should be a strong nexus between patient benefit and what are considered to be quality improvement activities. We believe the standard should be very narrow to prevent the plans from creatively categorizing activities as quality improvement when they are in fact more administrative in nature. In this regard, for example, care coordination activities that directly impact clinical outcomes should be recognized as medical expenses for purposes of the MLR numerator only if they are performed by physicians or other clinicians.

Actuarial Soundness, Rate Certification, and Contract Provisions

The AMA commends CMS’ efforts to increase transparency and accountability in how states determine whether the capitation rates paid by states to managed care organizations (MCOs) are actuarially sound. We believe that policymakers have an obligation to fully fund Medicaid programs and develop realistic capitation rates that support enrollment and provision of necessary services to all enrollees and promote access to quality care. Requiring states to provide CMS with enough data for the agency to understand the assumptions and methodologies underlying the rates will help ensure MCOs meet their obligation to provide timely access to quality care for all Medicaid beneficiaries. These important safeguards will improve the Medicaid program for all stakeholders.

With regard to CMS' rate certification process, we have concerns that physician payment rates will not be considered in the standard review process. The preamble to the Proposed Rule states that, in the event that concerns arise regarding timely access to services and coordination and continuity of care, the rate certification review would explore whether physician rates are sufficient to support the MCO's obligations. We urge CMS not to wait to examine physician rates until a problem is identified. Physician payment rates should be based on realistic costs of care and are an essential element of the capitation rate-setting. In order for CMS to thoroughly review the data, methodologies, and underlying assumptions used to set capitation rates, we believe physician payment rates must be submitted by the state, including any base, withholding, or bonus payments to be paid under an incentive arrangement with physicians. We urge CMS to require states to submit physician payment rates for certification and approval by CMS.

The AMA appreciates CMS' recognition in section 438.6(c) that state direction of provider payments through an MCO is a useful and effective tool to improve access to care. The AMA supported the enhanced payment rates for primary care physicians established by the ACA. Due to those targeted payment increases, access to care was improved when more primary care physicians were willing to see Medicaid patients. We applaud the agency's willingness to permit states to build on the effectiveness of that program. However, it is unclear in the language of section 438.6(c)(iii) whether and how states are permitted to differentiate based on provider type. As written, the rule may be interpreted to allow states to direct certain payments only if the payment amount is uniform across all provider types, specialties, and settings. We urge CMS to clarify section 438.6(c) to allow states to direct payment amounts for certain services to providers of differing types, specialties, and settings. This way, initiatives such as the enhanced payments for primary care in the ACA can continue.

Under section 438.807, CMS may defer or disallow portions of federal matching funds if a state's submitted contract is non-compliant with the federal requirements. We urge CMS to include in this section a safeguard to protect physicians from non-payment should CMS withhold funding from a state. Regardless of the actions taken between a state and CMS, physicians deserve to be paid for services provided to Medicaid beneficiaries that may be covered under the contract in dispute. To allow otherwise would create too much uncertainty for physician practices that may already face the financial burden of inadequate payment rates for services provided to Medicaid patients.

Prescription Drug Coverage

CMS proposes to add new contract provisions for managed care plans that are contractually obligated to provide coverage of covered outpatient drugs. These provisions would clarify that plan contracts covering outpatient prescription drugs must adhere to federal Medicaid requirements applicable to state programs directly, including the amount, duration, and scope of coverage, coverage limits, utilization management, and prior authorization. Thus, for example, CMS proposes that Medicaid managed care entities must add Drug Utilization Review (DUR) activities to their Medicaid managed care prescription drug benefit, as well as prior authorization procedures. In general, we are concerned that DUR programs will create barriers to treatment that can disproportionately burden those who are medically fragile, or those who have multiple chronic conditions, e.g., potentially impacting millions of Medicaid enrollees. Furthermore, we oppose regulatory and insurance practices that undermine the clinical judgment of treating physicians who better understand the risks and benefits of a course of treatment to their patient, as well as their patient's preferences, than a third party can do. We are concerned about the addition of mandatory utilization review controls, especially since the details will depend upon implementation by

each plan. It will therefore be important that plans be transparent about their DUR activities and be required to make information about their programs publicly available, beyond reporting to HHS. We also recommend that DUR programs be added to the ongoing state monitoring activities conducted by HHS as part of its oversight responsibilities.

We are concerned that while the Proposed Rule allows states to permit MCOs to maintain their own formularies as long as they meet the standards imposed by the Medicaid rebate statute, section 1927 of the Social Security Act, there are no proposed minimum formulary requirements. With an increasing number of states requiring persons with disabilities, seniors, and persons who are medically frail to enroll in Medicaid managed care, we believe there should at least be the same protections, such as those applicable to the six protected classes of drugs under the Medicare Part D program, applied to Medicaid managed care, including prohibiting step therapy for enrollees already taking a drug, and other onerous prior authorization requirements. These Part D protections are designed to “mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations” (CMS Medicare Part D Manual, Ch. 6, section 30.2-5). We recommend that CMS add language to the regulatory text that provides that managed care entities that cover the six protected classes of drugs under Medicare Part D (e.g., immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic classes) be prohibited from implementing prior authorization or step therapy for enrollees who are currently taking a drug. This prohibition should apply to those beneficiaries already enrolled in the plan as well as new enrollees actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan.

We support the proposal to require managed care plans to respond to prescription drug prior authorization requests within 24 hours, as well as providing for an emergency 72 hour supply of medications, as in fee-for-service prescription drug coverage. These consumer protections are just as important for Medicaid managed care enrollees as for fee-for-service beneficiaries. However, we are concerned that the Proposed Rule is not clear enough to ensure enrollees’ rights to obtain non-formulary drugs or drugs for off-label uses. The final rule should expressly provide for an exceptions process and clear appeals rights to ensure that Medicaid enrollees can access non-formulary drugs and prescription drugs for off-label uses to more fully align these regulations with requirements for health insurance plans sold through the Exchanges.

Allowing Inpatient Care for Short-Stays in Psychiatric Facilities for Psychiatric and Substance Use Disorder Treatment

The AMA strongly supports the proposed provisions that would lift the current decades-old Medicaid ban on funding inpatient care for short-stays—defined as 15 days per month—for psychiatric and substance use disorder (SUD) treatment at psychiatric facilities with more than 16 beds. We agree that this proposal is necessary due to access issues for short-term inpatient psychiatric and SUD treatment—there simply are not enough inpatient beds for treatment, especially for people in crisis, and without a bed, many end up on the street or in jail. Moreover, at the same time that beds in freestanding psychiatric facilities and psychiatric units in general hospitals have declined in the past several years, opioid abuse, misuse, and overdose, have reached epidemic levels. While this is not a magic bullet, and does not take the place of more needed investment in community-based treatment resources, it is a step in the right direction, and the AMA applauds CMS for its leadership in allowing managed care plans the flexibility to cover this treatment.

State Monitoring and Information Transparency Requirements

We applaud CMS for expanding and making more explicit the obligations on states to monitor the Medicaid managed care program. Many states have done a poor job overseeing Medicaid managed care programs and consequently some Medicaid patients have had difficulty accessing the full spectrum of care they need. Given the history of state monitoring, we are concerned that the Proposed Rule gives states too much leeway to develop their own system of oversight. We urge CMS to provide more specific requirements and guidelines for the state monitoring program. Importantly, we urge CMS to require comprehensive transparency and stakeholder engagement requirements in the state monitoring program.

We also urge CMS to focus state monitoring requirements on Medicaid's equal access requirements and physician payment rates. Medicaid MCOs should provide sufficient physician payment levels, at a minimum of 100 percent of Medicare's rates, to secure adequate access to physicians and quality of care provided to patients. Countless research studies have shown that physician payment rates are directly linked to a physician's willingness to accept Medicaid patients. Yet Medicaid payment rates are too often inadequate. Because of that, physicians are less likely to accept Medicaid patients than to accept patients covered by Medicare or private insurance. Without enough Medicaid-participating physicians to care for the Medicaid population, beneficiaries are likely to face barriers to care. Especially in the aftermath of *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015), it is incumbent upon CMS to aggressively protect beneficiaries' access to care and ensure physicians receive fair and adequate payment. As part of their access review, we urge CMS to require states to submit cost studies, physician payment rates, the number of physicians accepting new Medicaid patients, and an analysis of access in Medicaid compared to those in private group plans and Medicare and to make the information publically available. Payments made under Medicaid managed care programs are taxpayer dollars and the public deserves to know how these dollars are being spent.

We also appreciate CMS' recognition of the importance of transparency and efforts to improve the availability of information about MCOs. Advocates have often encountered difficulty obtaining information on managed care operations and services from states and MCOs. Section 438.10(c) greatly expands transparency by requiring states to provide on the state website information important to potential enrollees, enrollees, and the public such as enrollee handbook and plan policies. Under the Proposed Rule, however, some information will only be available to current enrollees. We recommend that CMS make publicly available and easily accessible all information available to plan enrollees. Further, we support the requirements in section 438.10(f) that MCOs must provide enrollees with notice of provider termination. However, we are concerned that notice is only required for enrollees that were seen by the provider on a "regular" basis. "Regular" is undefined. Many Medicaid patients may have important relationships with providers that they visit infrequently. For example, a patient may visit her obstetrician-gynecologist once a year, but have a patient-physician relationship that is nevertheless important to preserve. We recommend that CMS require MCOs to notify enrollees of the termination of any provider the enrollee has visited.

Network Adequacy Standards

The AMA is very supportive of the addition of new network adequacy requirements in the Proposed Rule and appreciates CMS' movement toward more meaningful requirements for MCOs and other managed

care plans. However, given growing network adequacy concerns in Medicaid managed care plans, we ask that CMS go even further than the changes proposed in this regulation.

State Enforcement

For example, while the Proposed Rule clarifies that CMS considered various standards for network adequacy requirements, we are concerned that the decision to maintain the current regulatory framework, e.g., relying largely on insurer attestation and certification to verify network adequacy, will only perpetuate network inadequacies. We think it is critical that CMS require state regulators to establish themselves as the primary enforcer of network adequacy requirements.

To further this goal, in section 438.207(a), we suggest requiring that state regulators actively approve networks submitted by MCO and other managed care entities, rather than reviewing them as needed. Furthermore, under section 438.207(c), we ask that CMS require MCOs and other managed care entities to regularly update their networks, submitting any material changes to the networks to state regulators so that they may determine possible network inadequacies. Should a material change impact the adequacy of the network, it is critical that patients be held harmless, and health plans be held responsible, when covered services are only available from out-of-network providers.

Alternative Processes

The AMA recognizes that there may be the rare occasion when a health plan may not be able to provide needed care in-network. In such situations, the health insurer must establish an alternative process for providing access to covered services that ensures the patient receives the care in a timely manner and at no additional costs to the patient than if the providers had been in-network. The use of such processes by health plans should be monitored by regulators to ensure that they are never being used as an alternative to an adequate network.

Measurable Standards

Under section 438.68(b), the AMA is very pleased to see a focus on measuring network adequacy for specific services, but asks that CMS add additional standards to this section. The AMA strongly supports new requirements that states develop time and distance standards to measure access, but believes that time and distance standards alone cannot create as complete a picture of a network as needed to determine true adequacy. Specifically, the AMA asks CMS to consider requiring that states not only adopt time and distance standards (section 438.68(b)(1)) to measure access to specific providers, but also require provider-to-patient ratio standards, wait time minimums and access to alternative office hours (e.g., evening/weekends) requirements. We also encourage CMS to require that time and distance standards incorporate travel on public transportation if heavily utilized in a geographic region, given the reliance of many Medicaid enrollees on public transportation to access Medicaid services.

With additional quantitative and measurable standards, regulators will be able to not only assess whether providers are within specified distances from enrollees, but also whether the network has the capacity to serve everyone enrolled and whether there is enough diversity in provider availability to meet the needs of enrollees.

In our work with the states and the NAIC on the issue of network adequacy, we have maintained that states are best suited to establish the specific measurements within a national framework, and we continue to believe that states are in the best position to “plug” in those numbers. However, that in no way negates the need for strong federal oversight, especially in the Medicaid program. The AMA encourages CMS to closely monitor states’ development and implementation of these measurements, maintaining the possibility of establishing federal minimum requirements in the future, if needed.

Provider Types Subject to Quantitative Standard(s)

The AMA is very glad to see that CMS is requiring measurable standards for a broad list of provider types. In addition to the provider types listed, we ask that CMS include “subspecialists (adult and pediatric)” to ensure appropriate access to covered subspecialty care for Medicaid enrollees. Additionally, we encourage CMS to differentiate between pediatric and adult behavioral health in the list of provider types needing specific, quantitative measurement.

Transparency in Network Standards

Under proposed section 438.68(e), plans must publish their network adequacy standards. The AMA supports this section in order to increase transparency and encourages CMS to establish additional transparency by requiring plans to post their standards on their state Medicaid program pages as well as Healthcare.gov and Medicaid.gov.

Furthermore, in addition to publishing network adequacy standards, the AMA asks that MCOs and other managed care entities be required to publish their provider selection standards, making them available to the public. On several occasions in the Proposed Rule, HHS expresses the need to prevent discrimination against populations of enrollees. We have seen in the private market a trend toward selecting providers based on only economic criteria without considering their case mix or the population they serve, which, in turn, can exclude quality services for patients with extensive needs. It is critical that patients, physicians, regulators and other stakeholders are well aware of how providers are being selected and if quality, case mix, and other factors are being considered.

Exceptions Process

The AMA understands that regional situations may, on occasion, prevent networks from meeting state network adequacy requirements. We understand and support CMS’ efforts to establish an exceptions process after an evaluation of the number of providers in the geographic area. As stated in our comments above on alternative processes, we encourage CMS to protect patients in plans that have been granted exceptions and require plans to ensure access to covered services at in-network cost sharing levels.

Directories

We appreciate that CMS is proposing stronger standards for provider directories with new and detailed information to be available to enrollees. Medicaid enrollees need comprehensive, accurate and up-to-date information to make informed choices about their health care and their health plans. Particularly, we support the requirements that paper directories are updated monthly and that electronic versions are

updated within three days. Additionally, we support requirements that directories be available in machine-readable formats.

Program Integrity

The AMA is firmly committed to eradicating health care fraud. Misappropriation of health care dollars robs funds that could otherwise be devoted to patient care. At the same time, the vast majority of physicians are honest, and should not be subjected to overly restrictive or broad brush regulations that detract from patient care. We are concerned that the added compliance program requirements on MCOs in section 438.602 will drive MCOs to put more onerous administrative burdens on physicians under the guise of this rule, which will, in turn, deter some physicians from caring for Medicaid patients. Any program integrity safeguards implemented by MCOs should therefore be targeted and streamlined to identify and expel true fraudsters, and, at the same time, allow honest physicians to easily navigate patient interactions and clinical workflow.

Currently, Medicaid MCOs utilize their own provider enrollment and screening processes for contracted network providers. Under the proposed requirement in section 438.214, all Medicaid participating physicians and other health care providers would undergo the state's screening and enrollment process, even those that only treat managed care enrollees. We fear that the proposed requirement will be yet another administrative hassle for physicians and ultimately limit the number of physicians willing to participate in the Medicaid program. We are also concerned that it will create a backlog with the state Medicaid program and result in long wait times for physician enrollment. We therefore urge CMS to strike this provision. Physician screening and enrollment process should be streamlined to make it easier, not harder, for physicians to care for Medicaid patients.

In section 438.602, Medicaid MCOs would be permitted to keep overpayments identified and recovered from network providers. We are concerned that this section applies too broadly and may allow MCOs to develop their own definition of fraud, waste, and abuse that includes even inadvertent billing errors for services properly rendered. We recommend that CMS provide a clear definition that distinguishes fraud, waste, and abuse from clerical and billing errors. Further, to the extent that MCOs identify and retain overpayments due to clerical errors for services properly provided, we urge that CMS impose the same three year look-back period restriction on Medicaid MCOs that applies to Medicaid Recovery Audit Contractors under fee-for-service Medicaid arrangements.

Quality Measures and Ratings

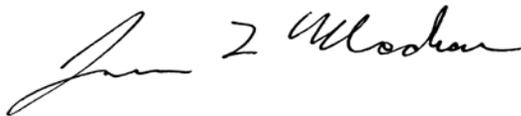
In proposing to extend the requirement for a quality improvement strategy to all state Medicaid programs as a general state plan administration requirement, it appears that states would have the option to include additional quality measures. However, the process for including additional quality measures is not yet clear, and we would caution CMS that physicians are already overburdened and overwhelmed with dealing with too much variation between quality reporting systems. A study conducted by the Rand Corporation for the AMA found that physicians were experiencing measure "fatigue" due to measurement chaos. As we have requested and commented on in the past, we urge CMS to ensure standardization and harmonization of quality measures and methodologies across reporting programs to reduce administrative burdens and simplify compliance.

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In addition, we would point out that although we understand that CMS is trying to align the Medicaid managed care regulations with other programs, we urge the agency to take into account the unique nature of Medicaid beneficiaries, many of whom tend to be sicker and have more health care needs than an “average” patient population. Therefore, we do not believe that CMS should look to the Medicare Advantage Star Ratings system as an appropriate model for a quality ratings system. The Medicaid managed care ratings system should weigh the variables of overall health disparities, lower health literacy, socioeconomic risk factors, and higher occurrence of comorbidities in this population.

In conclusion, the AMA appreciates the opportunity to provide comments and thanks you for considering our views.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD