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WHAT HEALTHCARE PROVIDERS SHOULD KNOW ABOUT THE PROPOSED MEDICAID MANAGED CARE REGULATIONS RELEASED LAST WEEK

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Basics: On May 26, 2015, the Centers for Medicare & Medicaid Services ("CMS") released a proposed rule to modernize Medicaid managed care regulations. This is the first major update to the Medicaid managed care in 42 C.F.R. Part 438 in over a decade. The proposed rule aims to align Medicaid managed care with Medicare Advantage and private market policies, bolster state delivery reforms, impose new quality ratings, set up best practices. The proposed rule impacts Managed Care Organizations ("MCOs"), Prepaid Inpatient Health Plans ("PIHPs"), Prepaid Ambulatory Health Plans ("PAHPs"), and Primary Care Case Managers ("PCCMs").

Our impression of this proposed rule is that it fundamentally seeks to increase protections for managed Medicaid enrollees by ensuring greater access to care and directing higher levels of expenditures into such care. However, the proposed also seeks to provide greater protections for managed Medicaid plans by increasing transparency with regard to the establishment of actuarially sound rates determined by states. Beyond those broader principles, it proposes to expand the scope of monitoring by CMS of states, and by states of plans. Plans would also be expected to incorporate numerous reforms related to program integrity and quality, many of which would potentially flow down to providers. As a result, providers should be concerned that without more specific instructions to plans, some plans may use these proposed rules to justify imposing more burdensome obligations on providers, which will add to existing and increased state requirements on providers. Unfortunately, the proposed rule does not provide any meaningful assistance to providers in seeking to ensure more appropriate and timely payment from plans. Finally, the proposed rule seeks to adopt a slew of new provisions involving health plan payment and delivery of Long Term Supports and Services ("LTSS") based on the increased prevalence of Medicaid managed care coverage of these services.

In this alert, we highlight important issues in the proposed rules affecting healthcare providers, including: (1) the integration of managed long term supports and services; (2) the "sidestep" of the IMD exclusion; (3) proposed network adequacy/accessibility standards; (4) proposed state enrollment of all managed Medicaid providers; (5) other proposed fraud and abuse provisions; (6) proposed revisions to appeals and grievances processes; and (7) propose changes to managed Medicaid coverage of outpatient drugs.

Integration of Managed Long Term Supports and Services ("MLTSS"): In this proposed rule, CMS addresses the increased coverage of long-term supports and services by managed care plans. While in 2004, only eight states had implemented Medicaid MLTSS programs, in 2014, an additional 12 states had implemented such MLTSS programs. The proposed rule would amend regulations throughout Part 438 to

Other Highlights

► Comments on the proposed rule are due July 27, 2015.

► A redline of the proposed rule to the current Part 438 rules is available here.

► The proposed rule proposes the establishment of a medical loss ratio of 85% with a ceiling of a "reasonable" limit for managed Medicaid plans starting 2017.

► The proposed rule purports to clarify the standards and process for establishing actuarially sound rates.

► The proposed rule would establish standards for incentive arrangements, risk corridors and withhold arrangements.

address concerns specific to the MLTSS population and the special vulnerabilities of this population. If adopted, these rules would provide more clear guidance to states that may be considering incorporating LTSS into their managed Medicaid systems.

In this proposed rule, CMS relied on 10 elements to guide its MLTSS proposals, including:

Adequate Planning: For example, ensuring appropriate state monitoring and accountability of the program, such as readiness reviews and additional standards for enrollee and potential enrollee materials.

Stakeholder Engagement: Creation of a structure for engaging stakeholders regularly in the ongoing monitoring and oversight of the MLTSS program.

Enhanced Provision of Home and Community Based Services: The proposed rule reinforces a longstanding trend in managed Medicaid programs in their focus on home and community based services, which helps ensure that enrollees are served in the least restrictive setting.

Alignment of Payment Structures and Goals: CMS has proposed to align payment to managed Medicaid plans to the goals of improving the health of populations, supporting the beneficiary's experience of care, supporting community integration of enrollees and cost reduction. This could include, without limitation, payment incentives to managed Medicaid plans to rebalance an enrollee population's use of home and community based services. The proposed rule also would require states include MLTSS in their monitoring of plans.

Support for Beneficiaries: CMS has proposed the establishment of a beneficiary support system, which would include choice counseling services, for beneficiaries with complex needs, such as those who receive LTSS. The proposed rules would also require: (1) an access point for complaints and concerns on the enrollment process, access to services and other related matters; (2) beneficiary education on the grievance and appeal process, the state fair hearing process, and enrollee rights and responsibilities; (3) assistance in navigating grievance and appeal processes; and (4) review and oversight of LTSS program data for the states to address systemic issues. CMS has also proposed to permit LTSS enrollees to change their Medicaid plans if their residential, institutional or employment supports provider terminates its participation with the enrollee's current plan.

Person-Centered Processes: The proposed rule would require identification, assessment and treatment/service planning for individuals receiving MLTSS to ensure that beneficiaries' medical and non-medical needs are met and that they have the quality of life and level of independence they desire.

Comprehensive, Integrated Service Package: CMS has proposed to expand current requirements so that Medicaid plans coordinate an enrollee's care between settings of care with services received from another Medicaid plan and with services received from fee-for-service Medicaid.

Qualified Providers: As discussed below, the proposed rules include access and availability standards for MLTSS providers, as well as standards related to the qualifications and credentialing of providers. CMS has also proposed requiring states to establish a uniform credentialing and recredentialing policy addressing acute, primary, behavioral, substance use disorders, and LTSS providers, which potentially increase additional requirements on providers in addition to the state enrollment provisions,

► The proposed rule would only permit a state to direct a plan's expenditure for: (1) value based purchasing models; (2) participation in a multi-payer delivery system reform or performance improvement initiative; or (3) the adoption of a minimum fee schedule for particular services or to provide a uniform increase for providers of particular services.

► The proposed rule establishes state monitoring of plans, which must address various aspects of the managed care program, including claims management.

► CMS has proposed that a state must consider provider complaint and appeal logs in its plan monitoring activities .

► As part of CMS' proposal for increased state monitoring of plans, it would require plan readiness reviews. Provider/ stakeholder input is not contemplated in the proposed readiness review process.

► The proposed rules do not establish prompt payment requirements for payments from managed Medicaid plans to providers.

discussed below. However, we note that these access and availability standards for MLTSS providers do not appear to take into consideration the status of many users of MLTSS as dual eligible for Medicare and Medicaid; accordingly, even if a managed Medicaid plan may meet access and availability standards, the enrollee may still experience obstacles in accessing care if the Medicaid networks are not aligned with Medicare networks.

Participant Protections and Quality: CMS has proposed to require managed Medicaid plans to participate in state efforts to prevent, detect and remediate all critical incidents. The proposed rules would also incorporate MLTSS-specific elements into the state's comprehensive quality strategy.

"Sidestep" of the IMD Exclusion: Section 1905(a)(29) of the Social Security Act excludes federal financial participation for any medical assistance under Title XIX for services provided to an individual ages 21 to 64 who is a patient in an IMD facility. In a surprising change in policy, CMS has proposed to permit MCOs and PIHPs to receive a capitation payment from the state for an enrollee aged 21 to 64 that spends a portion of the month for which the capitation is made as a patient in an institution for mental disease ("IMD"). This proposal is limited to: (1) IMD facilities that are either a hospital providing psychiatric or substance use disorder inpatient care or a sub-acute facility providing psychiatric or substance use disorder crisis residential services and (2) stays for less than 15 days in a month.

This addresses a longstanding and growing issue in many states of a lack of access to short-term inpatient psychiatric and substance use disorder treatment. CMS based this new policy on the flexibility that managed care plans have under risk contracts to provide alternative services or services in alternative settings in lieu of covered services or settings if cost-effective, on an optional basis, and to the extent that the plan and the enrollee agree that such setting or service would provide medically appropriate care. CMS reasons that its proposal is sufficiently limited so as not to contravene the Medicaid IMD coverage exclusion.

CMS has requested comment on its proposal to permit payments to Medicaid plans for months during which an enrollee resided in an IMD in limited circumstances.

► The proposed rules may impose Medicaid payment rates on out-of-network hospitals that provide post-stabilization services.

► Plan subcontractors may now be required to agree in contract to comply with "subregulatory guidance" and upstream contractual provisions.

► The proposal would change the definition of "rural" for the purposes of permitting a single plan to operate in a county.

► The proposed rules include various provisions regarding care coordination for patients requiring MLTSS, which may help effectuate discharge of beneficiaries.

Proposed Network Adequacy/Accessibility Requirements: The proposed rule would require states to develop network adequacy requirements that apply to contracts covering medical services, behavioral health services and LTSS. States would be required to establish time and distance standards for certain network provider types, including: primary care (adult/pediatric); OB/GYN; behavioral health; specialist (adult/pediatric); hospital, pharmacy; and pediatric dental. In addition, in acknowledging the special situation of LTSS where the provider site is the enrollee's residence, CMS has proposed that states with managed Medicaid contracts covering LTSS develop: (1) time and distance standards for LTSS provider types in which an enrollee must travel to the provider to receive services and (2) network adequacy standards other than time and distance standards for LTSS provider types that travel to the enrollee to deliver services.

States would also be required to consider certain factors in developing its network adequacy standards. Factors include: anticipated Medicaid enrollment; expected utilization of services (taking into account the characteristics and health needs of the covered population); number and types of health care professionals needed to provide covered services; number of network providers that are not accepting new Medicaid patients; and the geographic location and accessibility of providers and enrollees. CMS noted that there are disparities in access to care related to demographic features such as race, ethnicity and language. Therefore, the proposed rule would require states to consider factors such as the ability of network providers to communicate with limited English proficient enrollees in their preferred language.

CMS recognizes that a state may need to grant an exception to its network adequacy requirements for certain MCOs, PIHPs or PAHPs. Thus, a state may grant an exception if the standard for evaluating the exception is

specified in its contract with the plan and it is based, at minimum, on the number of health care professionals in that specialty practicing in the service area.

Although CMS will provide some oversight, under the proposed rule, states will have the primary responsibility of monitoring their Medicaid managed care networks. Plans will be required to submit documentation to the state demonstrating network sufficiency, and the state will then have to certify to CMS that the plans have satisfied the network adequacy requirements. *CMS has requested comment on: (1) whether CMS should propose a different national type of measure for states to further define, such as provider-to-enrollee ratios, or whether CMS should permit states the flexibility to select and define the type of measure for the network's adequacy of the specified provider types; (2) whether CMS should define the actual measures to be used by states such that CMS would set the time and distance or provider-to-enrollee ratio standard per provider type, per county, or other appropriate geographic basis; (3) whether standards for behavioral health providers should distinguish between adult and pediatric providers; (4) CMS' proposed approach to exclude family planning providers to time and distance standards based on the Medicaid freedom of choice of family planning providers; (5) CMS' proposal that would permit states to grant exceptions to a MCO, PIHP or PAHP to the state established provider network standards; (6) approaches to measuring enrollee's timely access to covered services and to evaluating whether managed care plan networks are compliant with such standards; (7) the value of requiring some or all of the mechanisms for ensuring that network adequacy are met; (8) the appropriateness of CMS' proposal that states review network certification materials and submit to CMS on an annual basis; and (9)CMS' approach generally to the assurances of network adequacy in proposed 42 C.F.R. section 438.207.*

Proposed Requirement of State Enrollment of All Managed Medicaid Providers: Currently, states vary as to whether they require that network providers with MCOs, PIHPs, PAHPs and PCCMs be enrolled in the respective state Medicaid program. The proposed regulations call for the screening, enrollment, and revalidation by states of all network providers of MCOs, PIHPs, PAHPs, and PCCMs or PCCM entities, to the extent the primary care case manager is not otherwise enrolled with the state to provide services to Fee-for-Service ("FFS") beneficiaries. State enrollment of these providers would not obligate the providers to render services to FFS beneficiaries.

This proposed provision is a change from prior CMS policy. For example, when CMS implemented the requirement in section 6401 of the Affordable Care Act that states enroll all ordering and referring physicians or other professionals as participating providers, the regulations specifically excluded from enrollment requirements Medicaid providers that only order or refer services as part of a managed Medicaid network. Likewise, CMS has not interpreted the requirement in section 1902(a)(27) of the Social Security Act that states enroll "person(s) or institution(s) providing services under the state plan" to require states to enroll person(s) or institution(s) serving managed Medicaid patients.

The Secretary explains this change in position is based on reports of inconsistency in the application of provider screening and enrollment between the Medicaid fee-for-service and managed care settings and concerns about provider fraud. The Secretary also states that this requirement will ensure that providers who are unable to enroll in Medicaid FFS programs cannot simply shift participation from managed care plan to managed care plan to avoid detection.

The requirement would not, however, prohibit managed care plans from conducting additional provider screening if they so desired. *The Secretary specifically seeks feedback on this proposal, particularly as to whether this approach could curtail rapid network development while MCOs, PIPs, and PAHPs wait for the state to complete its enrollment and screening process.*

The proposed regulations further mandate that the state review ownership and control disclosures for the MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, and their subcontractors, under the same standards used to review ownership disclosures for FFS providers. Under the proposed regulations, at the time of contracting and at least monthly thereafter, the state is required to confirm the identity and determine the exclusion status of the MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, their subcontractors, any persons with an ownership or control interest, and any managing employees or agents. Should the state become aware of an exclusion, the proposed regulations require the state to notify the MCO, PIHP, PAHP, PCCM or PCCM entity as well as the Secretary. The state may continue an existing agreement with the MCO, PIHP, PAHP, PCCM or PCCM entity absent any direction from the

Secretary otherwise, but the state may not renew or otherwise extend the duration of an existing agreement unless the Secretary provides to the state and to Congress a written statement describing compelling reasons for renewing or extending the agreement despite the exclusion.

Other Proposed Fraud and Abuse Provisions: CMS has proposed program integrity regulations that generally apply to the state, MCO, PIHP, or PAHP directly. However, these proposed requirements impact providers because these plans are then obligated to include specific contractual obligations when they contract with each other and subcontractors. The effect on providers, though indirect, may nonetheless be significant.

For example, the existing regulation requires MCOs, PHIPs, and PAHPs to have administrative procedures in place to detect and prevent fraud and abuse. The proposed regulations are far more specific. The proposed regulations obligate the state to include in its contracts with an MCO, PIHP or PAHP a requirement that the MCO, PIHP, or PAHP, or subcontractor (when it has liability for claims) to, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. It then lists the specific compliance elements including, but not limited to:

- that the MCOs, PHIPs, and PAHPs report to the state anything that might impact a provider's ability to participate in the managed care program;

- that MCOs, PHIPs, and PAHPs conduct sampling or other methods to confirm that providers are actually rendering the goods and services being paid; and

- that MCOs, PHIPs, and PAHPs report any suspected fraud to the Medicaid Fraud Control Unit (the BMFEA in California).

The impact of these changes will be an increased focus on providers by yet another set of entities. One can anticipate increased audits and expenses to comply with increased inquiries. For providers that also take on risk from a managed care entity, the expectation is that such providers will have to include these elements in a compliance plan.

The proposed regulations also create new obligations for the MCOs, PHIPs, and PAHPs to coordinate efforts to ferret out and report perceived fraud, including:

- an obligation for the MCOs, PHIPs, and PAHPs to suspend payments to a provider if the state determines there is a credible allegation of fraud. This can be extremely disruptive for a provider and would cut off another increasingly important revenue source while the state conducts what can be an extremely lengthy review.

- an obligation for the MCO, PIHP, or PAHP to put in its contracts with providers that a network provider will "report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment." This is essentially a version of the 60-day rule in section 1128J(d) of the Social Security Act, which many have considered to not be directly applicable to overpayments from managed care entities to providers, so the proposed regulations attempt to make it applicable contractually. The definition of "overpayment" is broad under the proposed regulations, reading "any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under title XIX of the Act." CMS did not specify any lookback period in this provision.

While CMS has not specifically requested comments on the way in which these proposals may affect providers, providers may wish to comment on the impacts these proposals may have on their relationships with Medicaid plans.

Proposed Revision of Appeals and Grievance Procedures: The proposed rule would revise the appeal and grievance requirements on managed Medicaid to align those provisions with Medicare Advantage and private insurers. Importantly for providers, the proposal would limit a plan's internal appeal processes to a single level and would only permit a state fair hearing until after that internal plan appeal is exhausted. The proposed rules would

also permit a beneficiary reasonable access to and copies of documents relevant to claim for benefits. The proposed regulations would also further limit who at the plan can determine an appeal by prohibiting a subordinate of a prior decision-maker from determining the appeal.

CMS has requested comment on: (1) the exclusion of non-emergency transportation PAHPs from the appeal and grievance requirements; (2) the extent to which states and plans are currently using or plan to implement an online system that can be accessed by enrollees for filing and/or status updates of grievances or appeals (and if they are not, why not); and (3) CMS' proposal that a plan implement a reversed appeal decision within 72 hours.

Proposed Changes to Managed Medicaid Coverage of Outpatient Drugs: The proposed rule includes new contract standards for MCOs, PIHPs and PAHPs that provide outpatient drug coverage. Under new §438.3(s), MCOs, PIHPs and PAHPs are required to comply with the coverage requirements under Section 1927(k)(2) of the Affordable Care Act. MCOs, PIHPs and PAHPs may maintain their own formularies for the drugs that must be covered, but will still be required to cover a non-formularly drug (through a prior authorization process) when the drug: (i) falls under the scope of the contract; and (ii) is medically necessary. In the event the MCO, PIHP or PAHP is not contractually obligated to cover the drug or class of drugs, the state must cover the drug through its fee-for-service program.

The proposed rule includes several other requirements for MCOs, PIHPs and PAHPs that provide outpatient drug coverage. A MCO, PIHP or PAHP must: (i) report certain drug utilization data to the state so the state may apply for drug rebates; (ii) operate a drug utilization review program; and (iii) conduct prior authorization in accordance with Section 1927(d)(5) of the Act.

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