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Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule[1]

On April 25, 2016, the Centers for Medicare & Medicaid Services (CMS) released the much-anticipated final rule ("Final Rule") updating the Medicaid managed care regulations for the first time in a decade. As CMS noted in the preamble to the Final Rule, the number of Medicaid managed care programs has increased dramatically during the past 10-plus years, and the number of Medicaid beneficiaries enrolled in managed care has increased five-fold between 1992 and 2013 to include nearly 46 million as of July 1, 2013. Medicaid also has expanded during this time to include broader groups of beneficiaries, such as those persons who need long-term services and supports (LTSS).

The Final Rule – a sweeping 1,425 pages in length in display form – clarifies various requirements with which Medicaid managed care plans must comply when they serve Medicaid beneficiaries. Nonetheless, states retain considerable flexibility to develop their own standards for regulating Medicaid managed care plans, including with respect to network adequacy, beneficiary enrollment, and various beneficiary protections.

Among other changes that may be of interest to manufacturers of health care products, insurers, hospitals, physicians, and other providers of Medicaid-covered services, the Final Rule:

- Clarifies that state contracts with managed care plans must require that the plans comply with the coverage standards for covered outpatient drugs under Section 1927 of the Social Security Act, frequently referred to as the "Medicaid drug rebate provisions";
- Requires that state contracts with managed care plans obligate the plans to establish procedures to exclude utilization data for 340B covered outpatient drugs from drug utilization reports in order to prevent manufacturers from having to provide "duplicate discounts";
- Provides Medicaid beneficiaries with various protections related to enrollment, care management, and continuity of coverage;
- Revises the appeals and grievance procedures that must be implemented by managed care plans in order to better align them with those of Medicare Advantage and commercial plans;
- Provides new opportunities for states to increase access to behavioral health services for Medicaid beneficiaries;
- Establishes minimum federal standards for managed care plans' provider networks;
- Establishes a national medical loss ratio (MLR) of 85 percent; and
- Establishes a quality rating system to support states' efforts to advance delivery system reforms.

The Final Rule will be published in the Federal Register on May 6, 2016, and is available online here. The Final Rule is scheduled to become effective on July 5, 2016.

Medicaid Managed Care Coverage of Covered Outpatient Drugs

CMS finalized its proposal to require state contracts with managed care organizations (MCOs), prepaid ambulatory health plans (PAHPs), and prepaid inpatient health plans (PIHPs) (collectively "managed care entities"), that offer coverage of "covered outpatient drugs," (as that term is defined in Section 1927(k)(2) of the Social Security Act), to obligate the managed care entity to comply with the coverage standards under the Medicaid drug rebate provisions. Put simply, where managed care entities provide covered outpatient drugs, states must require those managed care entities to adhere to the same coverage standards that apply in Medicaid fee-for-service (FFS) for covered outpatient drugs. Managed care entities are permitted to create their own formularies, but there must be a mechanism for allowing patient access to medically necessary drugs not on the formulary, in accordance with the section 1927 requirements.

Medicaid and 340B: Prohibition Against "Duplicate Discounts"

To prevent states from seeking Medicaid rebates on drugs sold at the 340B ceiling price and dispensed to Medicaid beneficiaries – and thus prevent manufacturers from having to provide "duplicate discounts" – the Final Rule requires the contracts between managed care entities and states to require the managed care entities to establish procedures to exclude utilization data for 340B drugs from drug utilization reports to the state. CMS places the responsibility for compliance squarely on covered entities, plans, and states, but does not specify any specific or required methodology for doing so. CMS also acknowledges that the duplicate discount prohibition has applied to managed care utilization since the Affordable Care Act's enactment in 2010, and directs that "to the extent states believe managed care utilization data have not been reported correctly during those time periods, states should work with their managed care plans to correct the data and establish processes with the managed care plan to ensure managed care plan utilization data is properly reported under this final rule."

Beneficiary Protections

The Final Rule implements most of CMS's proposal to address a perceived "gap" in the existing managed care regulations regarding protecting beneficiaries during enrollment into Medicaid managed care, facilitating care coordination, and ensuring continuity of coverage for certain items and services, particularly during transitions in care between Medicaid delivery systems.

Enrollment: CMS affirmed that, with respect to voluntary managed care programs, states may use either an active choice process (under which a beneficiary is given time to make an affirmative election to receive services through managed care or FFS) or a passive enrollment process (under which beneficiaries are automatically enrolled in managed care but may elect to opt out and move to the state's FFS delivery model within a certain period of time). States must make enrollment counseling services available to new enrollees and enrollees who have an opportunity to change their enrollment.

Care Coordination: In order to help improve health outcomes, CMS finalized its proposal to establish minimum standards for care coordination, patient assessments and treatment plans. The Final Rule requires that Medicaid and CHIP plans coordinate with one another, and with Medicaid FFS, in order to ensure that individuals can make smooth transitions between different care settings. Furthermore, CMS finalized its earlier proposal to require plans to complete an initial health risk screening of all new beneficiaries within 90 days of their enrollment. And, in the case of enrollees with special health care needs and/or enrollees who rely on LTSS, MCOs must develop a patient-specific treatment plan based on the initial assessment and ensure that the treatment plan is regularly updated.

Transition of Care Between Medicaid Delivery Systems: CMS finalized various transition of care requirements for Medicaid beneficiaries transitioning from one delivery system to another within Medicaid. CMS confirmed that states may design their own transition policy, so long as it meets federal minimum standards; states similarly have the flexibility to identify the specific enrollees for whom MCOs must provide transition of care services. As CMS explained in the proposed rule, the transition of care policy applies to prescription drugs if the MCO is required to cover drugs.

Appeals and Grievances

The Final Rule revises aspects of the Medicaid and CHIP managed care appeals process in order to better align this process with those of Medicare Advantage and commercial plans. According to CMS, this will provide consumers with a more streamlined appeals process and allow health insurers to adopt more consistent protocols across product lines and markets. Specifically, the Final Rule aligns definitions (including "adverse benefit determination," "appeal," and "grievance"), as well as timeframes for the resolution of appeals. Such timeframes are now: within 30 calendar days for standard appeals (shortened from 45 days under current rules), and within 72 hours for requests for expedited appeals (shortened from three working days under current rules). The Final Rule further requires that enrollees exhaust a managed care plan's internal appeals process before requesting a state fair hearing.

Mental Health and Substance Use Coverage Provisions

The Final Rule also provides new opportunities for states to increase access to behavioral health services for Medicaid beneficiaries. Historically, federal matching funds were not available for mental health and substance use services provided to most patients at inpatient facilities containing more than 16 beds. However, under the Final Rule, CMS will allow states to make a capitation payment – and federal matching funds will be available – for certain behavioral health services provided to beneficiaries who have a short

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term stay of no more than 15 days in an Institution for Mental Disease, or IMD. Notably, States will have the option – but are not required – to provide such coverage.

Network Adequacy

CMS finalized, largely without modification, its proposal to establish network adequacy standards in Medicaid and CHIP managed care for key types of providers, while leaving states flexibility to set the actual standards. Upon implementation, states will be required to establish time and distance standards for primary care (adult and pediatric), OB/GYN, behavioral health (mental health and substance use disorder; adult and pediatric), specialist (adult and pediatric), hospital, pharmacy, pediatric dental, and "additional provider types when it promotes the objectives of the Medicaid program." CMS finalized the proposed minimum factors that a state must consider in developing its network adequacy standards – including but not limited to anticipated Medicaid enrollment, expected utilization of services, and the number of network providers not accepting new Medicaid patients – but CMS explicitly declined to be overly prescriptive, instead preserving state flexibility to determine network standards.

Transparency

The Final Rule seeks to improve transparency of Medicaid managed care quality information by requiring states to post on their websites accessible information on managed care plan accreditation status and annual external quality reviews. CMS also requires Medicaid managed care entities to make their provider networks and formularies available on their websites, as well as to provide formularies including tiering information upon request.

Medical Loss Ratio

CMS finalized its proposal to impose a national MLR of 85 percent on managed care entities in the development of their capitation rates. This means that insurers must spend at least 85 percent of their Medicaid revenue on medical care and other activities that improve overall quality, while the remaining 15 percent of Medicaid revenue may be spent on other expenses such as marketing, overhead/salaries, and administrative tasks. Notably, 85 percent is the industry standard MLR for the Medicare Advantage program and for large employers in the private health insurance market. States will use the MLR calculation in their rate-setting exercises for future years.

Quality Rating Systems

To support states' efforts to advance delivery system reform and improve quality, the Final Rule requires states to establish a Medicaid quality rating system developed by CMS or adopt an alternative Medicaid managed care quality rating system that would be subject to CMS approval. Through a public notice and comment process, CMS will develop performance measures and a methodology for a Medicaid managed care quality rating system that aligns with the quality indicators for qualified health plans on the Exchanges. States will not be required to implement a quality rating system until three years after CMS issues guidance regarding the measures and methodologies for its rating system. Additionally, CMS chose not to finalize its proposal that would have given states the option to default to the Medicare Advantage Five-Star Rating system for plans serving only dual-eligible beneficiaries.

1. Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, [CMS-2390-F] (April 25, 2016).