

Mintz Levin Health Law and ML Strategies Advisory

Over a Decade in the Making: CMS Releases Long-Awaited Medicaid Managed Care Rule

06.05.2015

BY [SUSAN BERSON](#), [ANDY SHIN](#), [ELLYN STERNFIELD](#), [PAMELA KRAMER](#), [LAUREN MOLDAWER](#),
AND [BRIDGETTE WILEY](#)

Introduction

On May 27, 2015, the Centers for Medicare and Medicaid Services (“CMS”) [published a 653-page proposed rule](#) affecting the thirty-nine states (plus the District of Columbia) that use managed care organizations (“MCOs”) to administer their Medicaid benefits. This represents the first major overhaul of the Medicaid managed care system since the rules were established in 2002, now covering approximately seventy percent of all Medicaid enrollees.

Public comments are due July 27, 2015, which gives health plans, providers, consumer groups, and even state Medicaid directors a narrow window to identify potential areas of concern and to propose solutions for formal CMS consideration. While some issues will align important stakeholder groups, others are likely to remain contested during the comment period and up to publication of the final rule.

As a backdrop leading to the publication of the proposed rules, the managed care landscape has become much more complex and variable among the states that have adopted this approach in their Medicaid programs. Because of this, CMS has been contemplating ways to ensure more consistent rules that promote adequate access to health services while also creating more synergy between Medicaid, Medicare, and even the commercial sector via delivery system reforms that improve quality and lower costs.

The proposed rule also addresses some areas of perceived inequity in the Medicaid program that range from behavioral and substance-abuse treatment to long-term care and insurance reforms akin to those in the Affordable Care Act (“ACA”), which was mostly targeted at commercial health plans.

But CMS’s ambitions in proposing the rules need to be tempered by the reality that state Medicaid programs are administered by the individual states: through federal regulations CMS can establish minimal standards for the state Medicaid managed care systems but states may enact state regulations or impose managed care contract terms that go farther than the federal requirements. The managed care community must view federal regulations as a starting, not an end, point.

CMS categorizes the massive Medicaid managed care proposed rule into several issue areas in its [Fact Sheet](#):

Beneficiary Experience

- Requires states to improve access to care through regular assessment and certification of a health plan’s provider network and time/distance standards to providers including behavioral health, pediatric dental, and pharmacy.
- Updates communication rules directed towards Medicaid/CHIP beneficiaries to include electronic methods, non-English language options, and additional information in provider/drug formulary directories,



[Susan Berson](#), *Member*



[Andrew Shin](#), *Director, Health Care Policy & Life Sciences – ML Strategies*



[Ellyn Sternfield](#), *Of Counsel*



[Pamela Kramer](#), *Of Counsel*



[Lauren Moldawer](#), *Associate*

- Sets standards for care coordination, assessments and treatment plans that include care transition services, initial health risk assessments within 90 days of enrollment, and regularly updated assessments and treatment plans for beneficiaries with special health care needs or long-term services and supports.
- Creates a new enrollment selection period of 14 days to allow beneficiaries to research and select managed care plan options.

State Delivery System Reform

- Encourages participation in Medicare-led alternative payment models and initiatives.
- Establishes minimum reimbursement standards or fee schedules for providers that deliver a particular covered service.
- Clarifies “short-term stay” rule that managed care plans are able to receive capitated payments for beneficiaries who are admitted to an institution for mental disease (“IMD”) for no more than 15 days so long as the facility is an inpatient hospital or sub-acute short-term crises residential service.

Quality Improvement

- Creates a public notice and comment period to determine a core set of performance measures and improvement projects for states related to managed care plans.
- Establishes a Medicaid managed care quality rating system in each state that would report performance information on all health plans, akin to the Medicare Advantage (“MA”) and marketplace ratings.

Program and Fiscal Integrity

- Requires certain types of data to be used for rate setting purposes and the level of documentation and detail about the development of the capitation rates such as trend factors, adjustments and the development of non-benefit costs.
- Establishes a medical loss ratio (“MLR”) for both Medicaid and CHIP plans using standards similar to Medicare Advantage and the commercial market.
- Adds several components to fraud prevention efforts by implementing procedures for internal monitoring, auditing, and prompt referral of potential compliance issues, etc.

Managed Long-Term Services and Supports (“MLTSS”) Programs

- Affirms recent updates such as *Olmstead*, stakeholder engagement requirements, and provider credentialing in the development and implementation of MLTSS programs.
- Requires MLTSS-specific elements to be included in a state’s quality improvement strategy and reporting systems to protect MLTSS enrollees.

Children’s Health Insurance Program (“CHIP”)

- CMS proposes to align the CHIP managed care regulations, where appropriate.

Alignment with Medicare Advantage and Private Coverage Plans

- Importantly, CMS proposed where appropriate and possible, to align the Medicaid managed care regulations with those governing MA and private health insurance plans including the MLR, appeals and grievances, and marketing rules.

Finally, other highlights from the proposed rule include a requirement that Medicaid managed care entities offering outpatient drug coverage must now collect the necessary information for the states to include those



Bridgette Wiley, Associate

RELATED PRACTICES

- ▶ [Health Law](#)
- ▶ [Health Care Enforcement Defense](#)
- ▶ [Fraud & Abuse, Compliance & Regulatory Counseling](#)
- ▶ [Medicare, Medicaid & Commercial Payor Coverage & Payment](#)
- ▶ [Mintz Levin Center for Health Law & Policy](#)

RELATED INDUSTRIES

- ▶ [Health Care](#)

RELATED BLOGS

- ▶ [Health Law & Policy Matters](#)
- ▶ www.mlstrategies.com

managed care drugs in rebate invoices to drug manufacturers pursuant to the Medicaid Drug Rebate Program (“MDRP”) as well as modifications to the rules governing plan appeals and grievance procedures to increase uniformity with the procedures that apply to MA and commercial plans.

The discussion below provides a more in-depth analysis of a subset of these provisions.

Discussion

Alignment with Medicare Advantage and Private Coverage Plans

CMS proposes numerous changes aimed at aligning Medicaid managed care with other health care programs. The ultimate goal of these proposals is to promote consistency and, where possible, make it easier for states and health plans to manage the delivery of health care services across product lines.

Medical Loss Ratio

CMS proposes a nationwide minimum MLR of 85%, meaning 85% of the expenditures must be spent on care, and 15% on administrative costs. This change further serves the purpose of aligning Medicaid managed care program requirements with the standards set in the private health insurance and MA markets. CMS acknowledges that some states already require a minimum MLR, but pointed out that these standards vary significantly. CMS believes that a nationwide MLR will enable plans to set actuarially sound capitation rates and achieve consistency when offering products across multiple insurance markets. CMS does not establish a maximum MLR threshold, but encourages states to consider establishing appropriate maximum limits based on the services delivered.

CMS also proposes “minimum” standards for calculating and reporting MLR. The standards proposed more closely align with that of the private marketplace as opposed to MA, with CMS citing its belief in a need for greater similarity between Medicaid managed care plans and the commercial marketplace. However, CMS states that it proposes to incorporate MA standards where this need is outweighed by the need for protection for a public program.

Among the many standards for calculating and reporting MLR, one interesting proposal that stands out is the inclusion of fraud prevention expenditures as a cost of care in the calculation of MLR (rather than administrative cost), a significant difference from the MA MLR standards. But Medicaid managed care plans may only include fraud prevention expenditures up to 0.5% of premium revenue. CMS states that fraud prevention efforts do not include fraud recovery efforts.

Industry advocates are already speaking out both for and against many elements of the proposed MLR standards. It will be interesting to see the comments received and resulting CMS action, if any.

Marketing

In response to the ACA’s creation of Qualified Health Plans (“QHPs”) and general changes in the managed care delivery system, the rules propose three changes to the marketing regulations:

1. Amend the definition of “marketing” to specifically exclude communications from a QHP to Medicaid beneficiaries, even if the issuer of the QHP is also the entity providing Medicaid managed care.
2. Amend the definition of “marketing materials” to be broadly construed so that social media and electronic communication are encompassed in the definition.
3. Add a definition for “private insurance” to clarify that QHPs certified for participation in the exchanges are excluded from the term private insurance.

The proposed rules are intended to set minimum marketing standards that states can build upon. The goal is to provide clearer and more targeted Medicaid standards as the prevalence of health plans offering both Medicaid managed care plans and QHPs grows. CMS urges states to clarify marketing requirements in their contracts with

Medicaid managed care plans and make expectations clear so that there is no ambiguity for plans offering products across multiple business lines. Note that the rule also proposes to add PCCM entities to the umbrella of these regulations.

Appeals and Grievances

The rules propose changes to align appeals and grievances requirements with those applicable to MA, private health insurance, and group health plans. CMS's goal for these changes is to eliminate confusion for beneficiaries and create a more efficient, streamlined process.

Among the many proposed changes is the long overdue alignment of timeframe requirements to be consistent with the timeframes specific in the MA program.

CMS seeks comments on the extent to which states and plans are using or plan to use an online system that can be accessed by enrollees for filing and/or status updates of grievances and appeals, and comments on issues influencing decision not to implement such a system.

Network Adequacy Standards

One of the most anticipated provisions of this proposed rule focuses on how CMS would address network adequacy standards, as this rule follows two recent OIG reports indicating that beneficiaries in Medicaid managed care do not have timely and appropriate access to providers. In developing standards, CMS indicated it considered aligning Medicaid network standards to its approach for network adequacy under the Exchange and MA. Rejecting an approach mirroring MA that would have allowed CMS to set the minimum required number of providers by type and time and distance standards, CMS's proposal defers significantly to the states.

Time and Distance Standards

Under its proposed rule, CMS would require states develop minimum time and distance for the following provider types:

- Primary care, adult and pediatric
- OB/GYN
- Behavioral health
- Specialist, adult and pediatric
- Hospital
- Pharmacy
- Pediatric dental
- LTSS providers in which the enrollee must travel to the provider

Further, states must develop network adequacy standards other than time and distance standards for LTSS provider types that travel to the enrollee to deliver services. To increase transparency, states would be required to post their minimum standards online. And to provide CMS with greater oversight of access standards, CMS is also proposing that it has the ability to assess reasonableness of a state's standard, "should the need for such evaluation arise."

Access Standards

In addition to updating time and distance standards, CMS is proposing to update its regulations around the availability of services and timely access standards. Again, CMS is deferring to the states to develop timely access standards. CMS's proposed updates clarify that there must be timely access standards for all state plan services, but the services may be classified as routine, urgent, and emergency care. CMS also is seeking comments on how best to require states to monitor and assess these access standards.

Review and Approval of Managed Care Networks

The proposed rules would require Medicaid managed care plans to submit documentation to the state that their network is sufficient in number, mix, and geographic distribution to meet the state-set standards and the needs of anticipated beneficiaries. This documentation must be submitted annually and when there is a significant change in the provider network.

Quality Provisions

In addition to the changes discussed below, CMS's proposed rule would also require all states to develop a comprehensive quality strategy, update the external quality review process and protocols, and update external quality review organization ("EQRO") requirements and processes. Here, we highlight a few of the more interesting updates CMS is proposing with regard to quality.

Quality Rating System for Medicaid Managed Care Programs

One of the most notable quality provisions being proposed under this rule is the development of a quality rating system for Medicaid managed care plans. The proposed rating system would contain elements similar to the 5-star rating systems under MA and the marketplace. Specifically, the components of the rating system will include clinical quality management, member experience, and plan efficiency, affordability, and management, consistent with the rating system of QHPs in the marketplace. This would allow beneficiaries who may churn on and off Medicaid to better compare plans participating in Medicaid and in the marketplace.

CMS is also proposing significant flexibility in rating system to allow states to use alternative or preexisting methodologies. Further, for Medicaid plans that serve only dual-eligible individuals, CMS would allow states to default to the MA 5-star system to avoid duplication of reporting.

CMS anticipates developing the specifics of the rating system through a robust notice and comment period that would result in standards being developed three to five years prior to implementation.

Performance Measures

CMS is proposing to revise the regulations around performance measures that would allow it to specify standardized measures and topics for performance improvement projects ("PIPs") for Medicaid managed care programs. States would, however, be able to request an exception from these standardized performance measures. CMS is also requiring programs that offer managed long-term care to have specialized mechanisms to assess the quality of care of LTSS, such as rebalancing measures and community integration measures.

Monitoring and Readiness Review Requirements

CMS is proposing baseline standards for states to monitor their managed care programs. Specifically, CMS is proposing that states develop a monitoring system for all of its managed care programs that addresses specific elements such as the plan's administration and management; appeal and grievance systems; claims management system; and enrollee materials and customer services, among others. States would then have to provide annual assessments of the managed care program to CMS.

Furthermore, CMS is proposing to have a more active role in the Medicaid managed care readiness reviews. Readiness reviews are already required by regulation. CMS's proposal would require that the reviews be completed at least 3 months prior to the start of the program, that they cover minimum criteria outlined in the regulations, and that the results must be submitted to CMS.

Payment and Accountability Provisions

The proposed rules relating to payment and accountability again take steps to align Medicaid managed care regulations with those governing MA plans, while still giving deference to the states. Two areas of particular interest are the regulations relating to subcontractual relationships and program integrity.

Subcontractual Relationships and Delegation

CMS proposes changes that will clarify expectations for Medicaid managed care entities that enter into subcontracts and delegate responsibilities under its contract with the state. The proposed changes are modeled on the MA standards set for relationships between MA Plans and first tier, downstream, and related entities.

Program Integrity

CMS believes that the current regulations related to program integrity are "fairly limited in scope" and as such, proposes several new provisions aimed at alignment generally and overall strengthening of Medicaid managed

care program integrity.

Among the many proposed changes is the mandate for states to enroll all network providers that are not already enrolled to provide Medicaid FFS care. This enrollment would include provider screening and disclosure standards. Importantly, the proposal puts this obligation on the states and would not require network providers to also render services to FFS beneficiaries.

CMS states that this proposal would not prevent plans from doing additional screening, but hoped that, by delegating this responsibility to the states, it would eliminate duplicative screening by Medicaid managed care plans. The ultimate goal of this requirement is to prevent providers who have been barred from participating in Medicaid FFS from participating through a managed care plan.

CMS notably proposes changes that would update the numerous elements that must be included in Medicaid managed care compliance plans. One such element of particular interest is the requirements for the plan to suspend payments to a network provider for which the state determines there is a “credible allegation of fraud.” Under this proposal, the plan’s responsibility would be to promptly suspend payment at the direction of the state until the state notifies the plan the suspension is lifted.

Beneficiary Protections

Managed Long-Term Services and Supports

The proposed rule is largely a restatement of recent guidance and regulations that have updated the rules governing MLTSS and is consistent with the *Olmstead* community integration ruling,¹ stakeholder/public engagement requirements, and extensive MLTSS guidance published in May 2013.

The proposed rule sets forth a definition of LTSS to mean, “services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual’s home, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.” CMS states that they purposely defined LTSS in a way would allow for future innovation in what services are considered LTSS.

As noted above, CMS references ten elements identified in their 2013 guidance to be applied to MLTSS programs that include:

1. Adequate Planning
2. Stakeholder Engagement
3. Enhanced Provision of Home and Community-based Services
4. Alignment of Payment Structures and Goals
5. Support for Beneficiaries
6. Person-centered Processes
7. Comprehensive, Integrated Service Package
8. Qualified Providers
9. Participant Protections
10. Quality

Most of these elements have already been addressed in some form by states as they work to comply with the Home and Community-based Services rule and as they work to renew their Medicaid waivers. In many cases, the MLTSS portion of the proposed rule simply reinforces how MLTSS, as covered services under managed care contracts, would be included by other changes to the same extent as all other covered services. However, in other sections such as the “stakeholder engagement” category, CMS makes clear that issues specific to LTSS stakeholders may not be adequately addressed under current mechanisms such as the Medical Care Advisory Committee.

Additionally, as part of Element 5 above and to address the significant impact that provider network changes can have on the LTSS population, the proposed rule creates a new “for cause reason” to allow beneficiaries to switch to another Medicaid managed care plan or to normal FFS in states that do not permit plan switching at any time, if there is termination of a provider from their MLTSS network that would result in a disruption.

Medicaid Managed Care Continuity of Care and Transition Provisions

Currently, the only explicit transition of care standards focus on when a beneficiary is mandated into a single plan in a rural area. CMS proposed a new set of regulations for transition of care standards for all Medicaid beneficiaries transitioning from one delivery system to another within Medicaid (even MCO to MCO). The new standards expand the focus beyond primary care when considering care coordination and aim to strengthen the role of the assigned care coordination while ensuring there is more accurate and timely data gathering and sharing. Additionally, managed care plans would be required to complete an initial health risk assessment within 90 days of enrollment, and to maintain and share beneficiary health records, akin to current Medicare requirements.

Enrollee Materials and Information Standards

CMS proposes to update its regulations at 42 CFR §438.10 related to informational and communication standards for states and Medicaid managed care plans. The rule proposes standards related to the information that must be provided to prospective enrollees and managed care enrollees, as well the standards by which these materials must be provided electronically and in alternative formats.

CMS is also considering requiring that the provider directory data be held in a standardized format and be available through standardized application programming interfaces (“APIs”) so that CMS and states can “plug in” to the data and perform accuracy checks.

Standard Contract Provisions

CMS is using the proposed rule as an opportunity to make several changes to the existing regulations governing Medicaid managed care contract terms and adds a number of new standards.

Coverage of Outpatient Drugs

CMS proposes several new standards for Medicaid managed care contracts that include coverage of outpatient drugs. These standards include:

- Reporting drug utilization data necessary for the state to bill for rebates no later than 45 calendar days after the end of each quarterly rebate period.
- Establishing procedures to exclude utilization data for drugs subject to discounts under the 340B Drug Pricing Program. CMS notes that such mechanisms are necessary to ensure that drug manufacturers do not incur duplicate discounts on these drugs.
- Establishing and operating a drug utilization review (“DUR”) program that complies with the state’s standards when providing coverage through fee-for-service (“FFS”). The plan would have to provide a detailed description of its DUR program activities to the state on an annual basis.
- Responding to requests for authorization for a covered outpatient drug by telephone or other telecommunication device within 24 hours of the request and dispensing a 72 hour supply of a covered outpatient drug in an emergency situation.

Coordination of Benefit Requirements for Plans Covering Dually Eligible Individuals

CMS proposes to delegate the state’s coordination of benefits responsibility to Medicaid managed care plans serving dual eligible individuals. In other words, plans that serve dual eligible individuals would be responsible for the automated crossover claims process. Under FFS, when a provider submits a claim to Medicare for a dually eligible individual, there is an automated crossover claim submitted to Medicaid for the applicable cost sharing. This proposal would require Medicaid managed care plans be responsible for the automated claims crossover process for their members, with the goal of reducing the administrative burden for providers and thereby encouraging providers to serve Medicare-Medicaid dually eligible enrollees.

Actuarially Sound Capitated Rates for Medicaid Managed Care Contracts

CMS proposes to revise the Medicaid managed care rate setting framework. The proposed rule expands on the

existing definition of actuarially sound capitation rates, sets forth the standards that capitation rates must meet, outlines the steps that states must follow when setting rates, and specifies the contents of the rate certification.

Standards for Actuarially Sound Capitation Rates

Capitation rates must be reviewed and approved by CMS as actuarially sound. Under the proposed rule, capitation rates would be actuarially sound if the rates are "...projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract." The rule sets out specific standards states must follow in developing actuarially sound capitated rates.

Steps for Developing Actuarially Sound Capitation Rates and Rate Certification

CMS believes that setting clear standards for rate development, which are documented in the rate certification, support its goals of having a managed care system that operates with a high degree of fiscal integrity. CMS's proposed rule outlines steps required for developing actuarially sound capitation rates, standards for each step, and the contents of the rate certification that must be submitted to CMS for review and approval. We provide an overview of the steps in Appendix 1. CMS solicits comments from stakeholders on whether additional or alternative steps are appropriate.

Special Contract Provisions Related to Payment

Risk-Sharing Mechanisms

CMS proposes to build upon and update existing regulations related to risk-sharing mechanisms, incentive arrangements, and withhold arrangements. The proposed rule would establish the basic requirement that if a payment arrangement between the state and a managed care plan applies a risk-sharing mechanism, such as reinsurance, risk corridor, or stop-loss limits, it must be described in the contract. CMS believes that states should consider the parameters of the new proposed standards on a minimum MLR when developing risk sharing mechanisms to ensure upper and lower bounds are within those standards, but CMS has not made this a standard. CMS requests comment on this approach.

Incentive and Withhold Arrangements

CMS proposes to maintain the existing standards for incentive arrangements in Medicaid managed care contracts, which includes i) they are fixed in time, ii) they are not subject to automatic renewal, iii) they are available to both public and private contractors under the same terms of performance, iv) they are not conditioned on intergovernmental transfer agreements, and v) they are necessary for the specified activity and limited to 5% of the certified capitation rate. CMS also proposes to add a new standard that incentive arrangements be designed to support program initiatives tied to targets, performance measures, and quality-based outcomes. CMS requests comment on whether the existing 5% upper limit on the amount attributable to incentive arrangements is sufficient or if it is a barrier.

The proposed rule also adds standards for contracts that include withhold arrangements. The contract must meet the same standards as incentive arrangement contracts, with the exception of the 5% upper limit. The contract must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the plan's financial operating needs accounting for the size and characteristics of the populations covered under the contract, and its capital reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be submitted as part of the documentation required with the rate certification.

Delivery System and Provider Payment Initiatives

CMS proposes to formalize its policy on the extent to which a state may direct a Medicaid managed care plan's expenditures under a risk contract. The proposed rule begins with the general rule that the state may not direct the plan's expenditures under the contract and then provides three categories of exceptions. Under the proposed rule's exceptions, states may require the plans to:

- implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services;
- participate in a multi-payer delivery system reform or performance improvement initiative; and
- adopt a minimum fee schedule for all providers who provide a particular service under the contract, or provide a uniform dollar or percentage increase for all providers who provide a particular service under the contract.

The state would be required to obtain prior approval from CMS prior to implementing arrangements that direct the plan's expenditures. CMS believes that by proposing ways that a state may set parameters for how expenditures under the contract are made, it will move toward its goal of enabling states to incentivize and retain certain types of providers to participate in the delivery of care to Medicaid beneficiaries under managed care arrangements.

Encounter Data and Health Information Systems

CMS is also proposing several changes related to encounter reporting and health information systems to better align Medicaid requirements with ACA requirements. Much of the burden of these requirements will fall on the states. For example, the proposed rule requires that state claims processing and retrieval systems "be able to submit data elements necessary for Medicaid program integrity, oversight, and improvement." It also requires that specific encounter reporting requirements be written into contracts with the managed care plans. The encounter reporting by MCOs, PIHPs, and PAHPs must also be HIPAA compliant and in a format compatible with the Medicaid Statistical Information System ("MSIS"). States would also have to validate the accuracy and completeness of the encounter data prior to submission. Finally, CMS is also proposing the ability to withhold federal match from states that do not meet encounter reporting standards.

What to Expect Next

With already just over a week to digest the long-awaited update, health care stakeholders are on the clock to develop strategies that preserve and/or change a proposed rule that touches everything from network adequacy to quality improvement initiatives. For instance, health plans had already voiced objections to the medical-loss-ratio provision in the proposed rule, even before the proposed rule was published.

Other details are now coming to light that may come as a disappointment to some Medicaid beneficiary advocates such as CMS's proposal around network adequacy standards, and specifically its decision to defer to these standards to the states rather than developing minimum time, distance, and access standards. Some states, especially states with mature Medicaid managed care programs, already have network standards for the provider types required under the proposed rule. Therefore, stakeholders may question whether the provisions related to network adequacy can sufficiently improve provider access in many state Medicaid managed care programs.

Other provisions may result in pushback from state officials. For example, CMS is proposing to insert itself into oversight functions that were historically left only to the states such as readiness reviews and annual assessments. Additionally, the proposed rule would include specific data collection and reporting requirements on the states while putting FFP at risk if the data is not accurate, timely, and complete. This would likely require significant investments by states to update their MSIS systems.

Other stakeholders such as providers and the biopharmaceutical industry must consider the impact of a litany of changes in the proposed rule that touch everything from alternative payment models to coverage of off-formulary drugs. With a rule of this size, stakeholders are still formulating their strategies to prioritize their policy goals through their state leadership (governors), congressional delegation members, and directly with Obama administration officials.

Ultimately, the Obama administration has used this proposed rule to make a clear policy statement that they intend Medicaid programs to catch up with the rest of the health care system, and Medicare in particular, with respect to insurance and delivery system reforms that increase access, improve quality, and lower overall costs.

Appendix 1. Steps of the Rate Development Process

Step	Standard	Rate Certification
Base data – Identify, collect, and develop appropriate base utilization and price data	States must provide the actuary with all Medicaid-specific validated encounter data, FFS data (if applicable), and audited financial reports for the three most recent and complete years prior to the rate period. Actuaries may use their professional judgment to determine which data is appropriate to use, but the data must be no older than three years and derived from the Medicaid population, or if unavailable, a similar population with appropriate adjustment.	The base data used (including what the state provided to the actuary, what the actuary requested, and why any base data was not provided by the state), and how the actuary decided which base data was appropriate to use, must be described.
Trend – Develop and apply appropriate trend factors	Trends must be reasonable and developed in accordance with generally accepted actuarial principles and practices, and based on actual experience from the same or similar populations. CMS solicits comments on whether additional parameters and standards should be established.	Each trend factor, including for changes in utilization and price of services, must be described with enough detail to allow CMS to understand and evaluate the calculation and reasonableness of the trend for the enrolled population and meaningful differences in how a trend differs between the rate cells, service categories, or eligible categories.
Non-benefit component of the rate – Develop the non-benefit component of the rate to account for reasonable expenses	The non-benefit component of the rate must include reasonable expenses related to administration, taxes, licensing and regulatory fees, reserves, profit margin, cost of capital, and other operational costs. The foregoing must be related to the MCO's, PIHP's, or PAHP's provision of state plan services to Medicaid enrollees.	Each component must be described with enough detail to allow CMS to identify each type of non-benefit expenses that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense.
Adjustments – Make appropriate and	Adjustments must reasonably support the development of an	Adjustments must be described with enough detail to allow CMS to

reasonable adjustments	<p>accurate data base for rate-setting, address appropriate program changes, reflect the health status of the enrolled population, or reflect non-benefit costs.</p> <p>CMS notes that it has not identified specific adjustments that it finds permissible instead of requiring additional justification because it believes to do so might prevent use of reasonable judgment. CMS solicits comment on this approach.</p>	<p>understand and evaluate how each material adjustment was developed, the reasonableness of the material adjustment for the enrolled population, the cost impact of each material adjustment and the aggregate cost impact of all material adjustments, where in the rate setting process the adjustment was applied, and a list of non-material adjustments used in the rate development process.</p>
------------------------	---	---

<p>Risk adjustments – Select an appropriate risk adjustment methodology and apply it in a budget neutral manner</p>	<p>Prospective or retrospective risk adjustment methodologies must be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.</p>	<p>Risk adjustments must be described with enough detail to allow CMS to understand and evaluate the data, model, and any adjustments to data or model to be used to calculate adjustment, and any concerns that the actuary has with the risk adjustment process.</p> <p>For prospective adjustments, a description of the method for calculating risk factors, reasonableness, and appropriateness of the method in measuring same, magnitude of the adjustment, and assessment of predictive value of methodology compared to prior rating periods must also be included.</p> <p>For retrospective adjustments, the party calculating the adjustment and the timing and frequency of the adjustment must also be included.</p>
---	---	---

Endnotes

¹ *Olmstead v. L. C.*, 527 U.S. 581 (1999) (holding that under the Americans with Disabilities Act, persons with mental disabilities must have access to the least restrictive setting and must have access to community-based services when the services are appropriate, the transfer to the community is not opposed by the individual, and the placement can be reasonably accommodated).

