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TO: **Memo Distribution List**

LeadingAge New York

FROM: Hinman Straub P.C.

RE: Explanation of Final Rule Regarding Medicaid and Child Health Plus

DATE: May 26, 2016

NATURE OF THIS INFORM ATION: This is information explaining the Medicaid and Child Health Plus "Mega Reg."

DATE FOR RESPONSE OR IMPLEMENTATION: The regulation is effective on July 5, 2016, but the compliance dates within the regulation vary greatly. See the memo text for applicable compliance dates.

HINMAN STRAUB CONTACT PEOPLE: Cheryl Hogan, Stephanie Piel, and Sean Doolan

THE FOLLOWING INFORMATION IS FOR YOUR FILING OR ELECTRONIC RECORDS:
Category: #10 Miscellaneous/Other Suggested Key Word(s):

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On May 6, 2016, the Centers for Medicare and Medicaid Services ("CMS") published the final rule substantially updating the regulations that have governed Medicaid managed care ("MMC") programs since 2002. The final rule aligns, where feasible, many of the regulations governing Medicaid managed care with those of other sources of coverage including Qualified Health Plans and Medicare Advantage plans.

The rule implements certain provisions of the Affordable Care Act of 2010 ("ACA"), as well as strengthens actuarial soundness payment provisions to promote accountability in rate making, and promotes quality of care and efforts to reform the health care delivery system. The final rule updates managed care regulations to reflect how services are being delivered, addresses new geographic areas, populations, and services being covered by managed care and strengthens program integrity standards. Finally, CMS has applied many of the requirements for MMC to Child Health Plus ("CHP").

The regulation is effective on July 5, 2016. Compliance dates vary based on the section of the regulation. Unless otherwise stated, compliance is required by the effective date. If a provision has a different compliance date, we note that in the discussion of the applicable provision. The Child Health Plus provisions do not generally apply in New York until April 1, 2019.

I. SETTING ACTUARIALLY SOUND CAPITATION RATES

In adopting this final rule, CMS reiterates its principle that capitation rates should be sufficient and appropriate for the anticipated service utilization of the populations and services covered under the contract and provide appropriate compensation to plans for reasonable non-benefit costs. Actuarial sound rates promote program goals such as quality, improved health, and community integration. Capitation rates should be adequate to ensure availability and timely access to services, adequate networks, and coordination and continuity of care.

A. Rate Development Standards

CMS adopted a six step process with standards at each step for establishing actuarial sound capitation rates that all states must follow in establishing capitation rates.

- Collect or develop base data from historical experience
  - 3 most recent years prior to the rating period of validated encounter data, FFS data, and audited financial reports; the primary source of utilization and price data should be no longer that the most recently completed 3 years
- Develop and apply appropriate and reasonable trends to project benefit costs in the rating period, including trends in utilization and prices of benefits
  - Must be reasonable and based on actual experience from the same or similar populations
- Develop reasonable, appropriate, and attainable projected costs for non-benefit costs in the rating period
  - Intended to cover administration, taxes, licensing and regulatory fees, reserve contributions, risk margin, cost of capital and other operational costs (e.g., integrated behavioral health treatment plans and activities that support health care

quality and care coordination) and must be associated with the provision of services to populations covered under the contract
    - May be developed at the aggregate level and incorporated at the rate cell level
- Make appropriate and reasonable adjustments to the historical data, projected trends, or other rate components as necessary
    - Must reasonably support the development of accurate data sets, programmatic changes, health status, or non-benefit costs
- Consider historical and projected MLRs
- Select an appropriate risk adjustment methodology applied in a budget neutral manner and calculate adjustments to plan payments as necessary
    - To be used for determining and adjusting for the differing risk between plans

In response to a comment regarding reimbursement for the Health Insurance Provider Fee, CMS notes that nothing in this rule changes existing guidance which provides that state can take both the fee and the non-deductibility of the fee into account when establishing capitation rates.

B. Contract Provisions Related to Payments

The final rule requires that all risk-sharing mechanisms (e.g., reinsurance, risk-corridors, stop-loss) be described in the contract. CMS initially proposed, but ultimately rejected, amending the definition of risk corridor to allow states and plans to apply risk corridors to only profits or only losses. The final rule requires that risk corridors account for upside and downside risk.

Incentive arrangements must likewise be described in the contract and may not result in payments above 105% of the approved capitation rate. Incentive arrangements must be for a fixed period of time, cannot be renewed automatically, must be made available to the public and private plans, cannot be conditioned on intergovernmental transfer agreements and must be necessary for specific activities, targets, performance measures, and quality-based outcomes that support program initiatives and are consistent with the state's quality strategy.

Likewise, withhold arrangements must be tied to meeting performance targets specified in the contract distinct from general operational requirements. A portion of the premium is withheld pending a determination that such performance targets have been achieved. Withhold arrangements are distinct from penalties. Penalties are an amount of the payment that is withheld unless the plan satisfies operational requirements of the contract. CMS notes that there is no federal authority for instituting penalties; rather, penalties are subject to authority granted under state law. Contracts with withhold arrangements must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound. The total amount of the withhold must take into consideration financial operating needs accounting for the size and characteristic of the populations covered under the contract, capital reserves, months of claims reserve, and other appropriate measure of reserves. Finally, CMS notes that unearned amounts under a withhold arrangement do not create a residual pool of money to be distributed to other plans. Amounts paid to other plans would have to meet the requirements for an incentive arrangement. Federal financial participation is only available for the withheld funds actually paid to plans for achieving performance targets.

CMS adopted the rule that, subject to certain exceptions, states may not direct plan expenditures under contracts to require plans to participate in delivery system and provider payment initiatives such as requiring plans to implement value-based purchasing models, participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiative, adopt a minimum and maximum fee schedule for classes of providers, and provide a uniform dollar or percentage increase for network providers.

All contract arrangements that direct plan expenditures must be approved prior to implementation. Such approval requires that the arrangement is based on the utilization and delivery of services, directs expenditures equally using the same terms of performance for a class of providers providing services, expects to advance at least one goal and objective in the quality strategy, has an evaluation plan to measure the degree to which the arrangement advances the goals and objectives in the quality strategy, does not condition participation on intergovernmental transfer agreements and may not be renewed automatically. The arrangement must use a common set of performance measures across all payers and providers, may not set the amount or frequency of the expenditures, and must not allow the state to recoup any unspent funds.

C. Rate Certification

In adopting the final rule, CMS sought to strengthen its approach to approving capitation rates by requiring consistent and transparent documentation. Plans must include rates in their managed care contracts and both the rates and the contract must be approved by CMS. Rates should be sufficient to support quality care, improved health, community integration, and cost containment. The actuarial certification should provide sufficient detail and documentation to enable other actuaries to assess the reasonableness of the methodology and assumptions. Certification to rate ranges will no longer be permitted; rather, certification must be to each rate cell. States may increase or decrease certified rates by up to 1.5% without submitting a revised certification.

1. Base Data

The certification must include a description of the base data used in the rate setting process. This includes the base data requested by the actuary, the base data that was provided by the State, and an explanation of why any base data requested was not provided by the state. The certification must also include a description of the determination of which base data set was appropriate for the rating period.

2. Trend

Each trend factor, including trend factors for changes in utilization and price, applied to develop the capitation rates must be adequately described with enough detail so that an actuary applying accepted actuarial principles and practices can understand and evaluate the calculation of each trend for the rating period and the reasonableness of the trend for the enrolled population and any meaningful differences in how trend differs between the rate cells, service categories, or eligibility categories.

3. Non-Benefit Component

The development of the non-benefit component of the rates to cover costs such as administration, taxes, licensing and regulatory fees, reserve contributions, risk margin, cost of capital, and other operational costs (e.g., integrated behavioral health treatment plans and activities that support health care quality and care coordination) must be adequately described so an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense.

4. Adjustments

All material adjustments must be described with enough detail so that an actuary applying generally accepted actuarial principles and practices can understand and evaluate how each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population, the cost impact of each material adjustment and the aggregate cost impact of non-material adjustments, where in the rate setting process the adjustment was applied, and a list of all non-material adjustments used in the rate development process.

5. Risk Adjustment

All prospective risk adjustment methodologies must be adequately described with enough detail so that an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

- The data and any adjustments to the data to be used to calculate the adjustment
- The model and any adjustments to that model to be used to calculate the adjustment
- The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations
- The magnitude of the adjustment on the capitation rate per plan
- An assessment of the predictive value of the methodology compared to prior rating periods
- Any concerns the actuary has with the risk adjustment process

CMS notes that risk adjustment must be budget neutral and cannot be used to increase payments across all Plans as this would be an acuity adjustment which is a permissible adjustment to be addressed according to the adjustments described in paragraph 4 above.

6. Certification and Submission

The state, through its actuary, must certify the final capitation rate paid per rate cell under each risk contract and document the underlying data, assumptions and methodologies supporting that specific capitation rate. Plans can be paid different capitation rates so long as each capitation rate per rate cell is independently developed and established in accordance with the above requirements. Any retroactive adjustment must be supported by rationale and the data, assumptions, and methodologies used to develop the magnitude of the adjustment must be

adequately described with enough detail to allow an actuary to determine the reasonableness of the adjustment. Retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment subject to CMS approval. States may increase or decrease the capitation rate per rate cell up to 1.5 without submitting a revised rate certification. However, such changes must be approved by CMS in accordance with contract approval requirements.

II. MEDICAL LOSS RATIO REQUIREMENTS

The MLR provisions apply beginning with the first rating period on or after July 1, 2017.

CMS believes that medical loss ratio ("MLR") calculation and reporting are important tools to ensure that capitation rates set for MMC programs are actuarially sound and adequately based on reasonable expenditures on covered medical services for enrollees. Therefore, the regulation requires that an MLR be calculated, reported, and used in setting capitation rates. The preamble to the regulation also clarifies that the regulation does not, in and of itself, require Plans as a matter of contract compliance to meet a specific MLR. In this vein, the regulation does not require payments to the state when a Plan fails to meet the minimum MLR, but permits states to impose such a requirement. If a state requires a remittance upon a Plan's failure to meet a specified MLR, the state must return the federal share of the remittance to CMS. States would have to determine a methodology for repaying such amounts and submit a report to CMS regarding the same.

States must ensure that their contracts with Plans that start on or after July 1, 2017 require Plans to meet the MLR standards. For multi-year contracts that do not start in 2017 (such as in New York), Plans must calculate and report an MLR for the first rating period that begins in 2017. A state's MLR reporting year is a period of 12 months that must be consistent with the state's rating period. In New York, rating periods are generally six or three months long, so it is unclear how the MLR reporting period will be set.

MLRs will be considered both prospectively and retrospectively. For purposes of setting capitation rates, rates must be set to achieve an MLR of at least 85%, calculated as described below. States can set a higher minimum MLR, but it still must be calculated consistent with the federal calculation. The proposed regulation does not set a maximum MLR, but provides that the MLR should "not exceed a reasonable maximum threshold that would account for reasonable administrative costs." The preamble to the regulation recommends that states set a maximum MLR so ensure that capitation rates are adequate.

Plans will also have to report the actual MLR at the end of year, and states will be required to take this into account in setting rates for future years.

A. Calculation

The regulation uses the same general calculation for the MLR as is used by the federal government for commercial insurance, but with differences as to what is included in the numerator and the denominator to account for differences in the Medicaid program.

Additionally, the calculation is over a 12 month period rather than a three year period as is the case for commercial coverage. The regulation states that all MMC populations will be aggregated for purposes of determining MLR, but gives states flexibility to choose to separate the MLR calculation by Medicaid eligibility group.

The calculation is:

$$\frac{\text{incurred claims + health care quality improvement activities + fraud and abuse activities}}{\text{premium revenue – taxes and fees}}$$

1. Items in the Numerator

   a. Incurred Claims

Incurred claims include:

- Direct claims that the Plan paid to providers (including under capitated contracts with participating providers) for services or supplies covered under the contract;
- Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported;
- Withholds from payments made to participating providers;
- Claims that are recoverable for anticipated coordination of benefits;
- Claims payments recoveries received as a result of subrogation;
- Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity;
- Changes in other claims-related reserves;
- Reserves for contingent benefits and the medical claim portion of lawsuits

Under the proposed rule, amounts Plans received from the state for purposes of stop-loss payments, risk-corridor payments, or retrospective risk adjustment were deducted from incurred claims, while payments to the state because of a risk corridor or risk adjustment calculation, were included in incurred claims. The final rule includes net payments and receipts related to risk share mechanisms as premium revenue in the denominator.

Plans must deduct overpayment recoveries received from participating providers and prescription drug rebates received and accrued from incurred claims.

Plans must include the amount of incentive and bonus payments made, or expected to be made, to participating providers and the amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, in incurred claims. The amount of fraud reduction expenses must not include activities specified in paragraph (c) below. Payments or receipts related to state mandated solvency funds must be either included or deducted from incurred claims, as applicable.

Plans must exclude the following from incurred claims:

- Non-claims costs, which include:
    - Amounts paid to third party vendors for secondary network savings;
    - Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management;
    - Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services;
    - Fines and penalties assessed by regulatory authorities;
- MLR payment amounts, if applicable;
- Amounts paid to participating providers as "pass through payments" (e.g., HCRA or GME amounts)

b. Health Care Quality Activities

Health care quality activities that can be included in the numerator include those activities permitted under the commercial insurance MLR rules, as well as activities specific to Medicaid managed care External Quality Review activities, and activities related to Health Information Technology and meaningful use.

CMS declined to explicitly list activities related to service coordination, case management, and activities supporting state goals for community integration of individuals with more complex needs, such as individuals using Long Term Services and Support ("LTSS") as activities that improve health care quality because it believes that these activities are already included in the definition of "activities that improve health care quality."

In response to comments, the preamble notes that payments to providers who do not qualify for the HHS meaningful use payments can be included in the numerator of the MLR calculation as activities related to Health Information Technology.

c. Fraud activities

Significantly, the final rule allows expenditures for fraud prevention activities "as adopted for the private market at 45 CFR part 158" to be included in the numerator. However, at this time, there are no fraud prevention activities adopted for the private market. As a result, it does not appear that Plans can include fraud prevention activities in the numerator of the MLR unless and until permitted in the commercial market.

2. Items in the Denominator

The denominator is the Plan's premium revenue minus the Plan's federal, state, and local taxes and licensing and regulatory fees.

The final regulation provides that premium revenue includes:

- State capitation payments for all enrollees under a risk contract, excluding payments made as pass-through payments;
- State-developed one time payments, for specific life events of enrollees (e.g., maternity kick payments);
- Other payments to Plans approved as payments under a withhold arrangement;
- Unpaid cost-sharing amounts that the Plan could have collected from enrollees under the contract, except those amounts the Plan can show it made a reasonable, but unsuccessful, effort to collect;
- All changes to unearned premium reserves;
- Net payments or receipts related to risk sharing mechanisms

The regulation clarifies that payments earned by Plans under a withhold arrangement, as described in section I.B above, should be accounted for in premium revenue and included in the denominator for purposes of the MLR calculation because the amount of the withhold is considered in the rate development process and reflected in the rate certification.

Federal and state taxes include all types of taxes except for federal income taxes on investment income and capital gains and Federal employment taxes.

The regulation allows Community Benefit Expenditures (CBEs), as defined in 45 CFR 158.162(c), to be deducted from premium revenue up to the greater of three percent of earned premiums or the highest premium tax rate in the applicable state multiplied by the earned premium for the Plan. This provision is consistent with the Medicare Advantage provisions.

3. Credibility Adjustments

In order to address special circumstances of smaller plans, the regulations include a credibility adjustment to the MLR. The credibility provisions are generally consistent with those used in the commercial market.

If a Plan's experience is non-credible, it is presumed to meet or exceed the minimum MLR. If a Plan's experience is partially credible, a credibility adjustment may be added to a calculated MLR. If a state requires payment for not meeting minimum MLRs, the credibility adjustment is added to the reported MLR calculation before calculating any remittances.

CMS will annually publish base credibility factors for Plans. The factors will be developed according to the following methodology:

- CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than one year of experience.

- CMS will calculate the credibility adjustment so that a Plan receiving a capitation payment that is estimated to have an MLR of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

- The minimum number of member months necessary for a Plan's MLR to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible Plan. Any Plan with enrollment less than this number of member months will be determined non-credible.

- The minimum number of member months necessary for a Plan's MLR to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible Plan will be greater than one percent. Any Plan with enrollment greater than this number of member months will be determined fully credible.

- A Plan with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

- CMS may adjust the number of enrollee member months necessary for a Plan's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of the regulation.

B. Reporting

States must require Plans to report the following information for each reporting year:

- Total incurred claims;
- Expenditures on quality improving activities;
- Expenditures related to fraud and abuse activities;
- Non-claims costs;
- Premium revenue;
- Taxes, licensing and regulatory fees;
- Methodology for allocation of expenditures;
- Any credibility adjustment applied;
- The calculated MLR;
- Any remittance owed to the state, if applicable;
- A comparison of the information reported in this report with the audited financial report required under the regulation;
- A description of the aggregation method used;
- The number of member months

States will determine the time frame and manner in which this report must be submitted, which must be within 12 months of the end of the reporting year. If a Plan uses a vendor to provide any claims adjudication services, the Plan must require the vendor to submit any information needed for MLR purposes within the earlier of 180 days of the end of the reporting year or 30 days from a request. If a state retroactively changes capitation rates after a report has been submitted, the

Plan must recalculate the MLR and submit new reports for affected reporting years. Reports must be certified by Plans.

C. State Oversight

States must report to CMS a summary description of the outcomes of the MLR calculations for each MLR reporting year for each Plan. The report must be included with that rate certification required under the proposed rule and must include the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each Plan.

The regulation requires states to develop an annual assessment on the performance of their managed care programs. This assessment includes reporting on the financial performance of each Plan. The final regulation clarifies that financial performance includes MLR experience. States will be required to publish the assessment annually on their websites.

The final regulation also adopts these MLR requirements for Child Health Plus.

III. MARKETING

Due to the creation of QHPs and changes in the managed care delivery system, the agencies revised the marketing rules applicable to MMC Plans as proposed. That is, the rule exempts from the definition of "marketing" communications from QHPs to MMC beneficiaries, even where the QHP is also the MMC Plan. Thus, Plans that offer both QHPs and MMC are able to market both products without violating the MMC "tie-in" prohibitions. The regulation also adds a definition of "private insurance" to clarify that QHP issuers are not private insurers for purposes of this rule. The regulation also clarifies that marketing includes the use of social media and other electronic communications. It specifically provides that unsolicited contact via email or text is prohibited as cold calling.

In response to comments, the agencies noted that a managed care plan sending information to its enrollees addressing healthy behaviors, covered benefits, the managed care plan's network, or incentives for healthy behaviors or receipt of services (for example, baby car seats) would not meet the definition of marketing, but the use of this information to influence an enrollment decision by a potential enrollee is marketing. With respect to marketing at public events, the agencies noted that providing information about a managed care plan's other lines of business at a public event where the Medicaid eligibility status of the audience is unknown would not be prohibited, but marketing materials at such events that are about the Medicaid health plan are subject to marketing restrictions.
Regarding information about redetermination eligibility, the agencies state that the permissibility of outreach to enrollees for eligibility redetermination purposes depends on the contract between the state and the Plan.

The final regulation also applies the Medicaid marketing requirements to Child Health Plus, except the requirement to consult with the Medical Care Advisory Committee.

IV. STANDARD CONTRACT PROVISIONS

A. CMS Approval of Contracts and Capitation Rates

CMS finalized its proposal to permit the establishment of contract review and approval timeframes through subregulatory guidance. CMS clarified in response to comments that only those states that require approval of contracts prior to the effective date are required to submit such contracts no later than 90 days before the intended effective date. The same timeframe is applicable to premium rates, as such rates must be included in the contracts.

B. Enrollment Discrimination Prohibited

CMS adds sex, sexual orientation, gender identify and disability to the list of protected categories for the purposes of prohibiting discrimination in enrollment. Plans are also prohibited from using any policy or practice that has the effect of discriminating based on race, color, national origin, sex, sexual orientation, gender identity or disability.

C. "In Lieu of" Services

CMS added a provision to the final regulation regarding so called 'in lieu of" services. These are services that are not part of the state plan but may be covered under the state plan in certain circumstances. A state can add coverage for in lieu of services to the contract, but Plans cannot be required to cover such services. If a Plan determines to cover in lieu of services, members cannot be required to use such services in lieu of state plan services. States would determine the alternate service or setting that is medically appropriate and is a cost effective substitute for covered services. This is not an enrollee-specific determination. Alternate service utilization and costs can be taken into account during capitation rate development so long as there is not a law or regulation that prohibits coverage of such services (e.g., IMD services).

D. Conflict of Interest Safeguards

CMS restates existing requirements to comply with applicable laws and conflict of interest standards, and adds a requirement to comply with Section 1557 of the Affordable Care Act, which prohibits discrimination in health programs. Contracts must also comply with conflict of interest safeguards applicable to state officers, employees and agents.

The regulation applies the existing Medicaid conflict of interest rules to Child Health Plus.

E. Provider Preventable Conditions

CMS continued the existing requirements with respect to reporting provider-preventable conditions and prohibiting payments for provider-preventable conditions.

F. State and Federal Audits

The final rule restates the rights of the state and federal government to audit and inspect Plans, and expands the audit right to include access to premises and physical facilities and equipment of contractors and subcontractors at any time. CMS also expanded the timeframe for the right to audit to 10 years and likewise, expanded the timeframe for which records must be maintained to 10 years from the final date of the contract period or the date of completion of any audit, whichever is longer. Audits may occur at any time, including outside of normal business hours.

This audit provision will apply beginning with rating periods beginning on or after July 1, 2017.

G. Audited Financial Statements

CMS finalized the requirement that Plans submit audited financial statements for Medicaid contracts annually and that states use this information as a source of base data for rate setting purposes. Such audits must be conducted in accordance with generally accepted accounting principles and auditing standards.

This provision will apply beginning with rating periods beginning on or after July 1, 2017.

H. Long Term Supports and Services

Contracts covering long term supports and services may include the provision of home and community based waiver services so long as those services are delivered consistent with the home and community based settings rule.

I. Pharmacy Management Requirements

The final rule requires contracts that require Plans to cover prescription drugs to include provisions extending the requirements of fee-for-service pharmacy programs to Plans. Coverage must be limited to outpatient drugs whose manufacturer has entered into a rebating agreement with the federal government, unless the drug is a single source drug or is an innovator multiple source drug and the drug is essential to the health of enrollees. Plans are permitted to adopt formularies, but must have an exception process for non-formulary covered outpatient drugs when there is a medical need.

Significantly, Plans must operate a drug utilization review program that has a prior authorization program capable of providing responses by telephone or other telecommunication device within 24 hours of a request for prior authorization and provides for the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation. The 24-hour timeframe applies to all prior authorization requests, regardless of whether the request is urgent. This will undoubtedly be an onerous requirement for Plans.

The drug utilization review program must be intended to assure that prescriptions are appropriate, medically necessary, and unlikely to cause adverse medical results. The program must educate physicians and pharmacists on identifying fraud, abuse, overuse and inappropriate

or unnecessary care and underutilization, appropriate use of generic products, therapeutic duplications, contraindications, interactions, dosage and duration of treatment, allergy interactions, and clinical misuse and abuse. Drug data must be assessed based on standards consistent with compendia and peer-reviewed literature. A drug utilization review program report must be submitted annually to the state.

Plans must report drug utilization data to allow the state to bill manufacturers for rebates and must, therefore, have a process for identifying 340B drugs to prevent rebates from being claimed for such drugs.

These provisions apply beginning with rating periods on or after July 1, 2017.

J. Medicare Cross-Over Claims

When states have coordination of benefits agreements with Medicare, and such states delegate responsibility for coordinating benefits for dual eligible members, contracts must require Plans to participate in the Medicare automated crossover process for dual eligible beneficiaries.

K. Patients of IMDs

CMS finalized this provision as was proposed to provide states the flexibility to pay capitation payments for enrollees aged 21 through 64 who are patients in institutes for medical disease (IMD) for psychiatric or substance use disorder services so long as the facility is 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 the length of stay is no more than 15 days during the period of the capitation payment. The services must meet the requirements of in lieu of services (i.e., be in the contract, voluntary for plans, and voluntary for members). States may use the utilization of IMD services in the rate setting process but must price the services at the cost of the same services available under the state plan.

V. OTHER PAYMENT AND ACCOUNTABILITY IMPROVEMENTS

A. Subcontractual Relationships and Delegation

Contracts with Plans must require that Plans maintain ultimate responsibility for complying with all of the terms and conditions of the contract with the state notwithstanding any relationship the Plan has with a subcontractor. Each agreement with a subcontractor must specify whether any of the Pan's obligations under its contract with the state are being delegated, that the subcontractor agrees to perform the delegated activities and reporting responsibilities, and provide for revocation or other remedies when the subcontractor has not performed satisfactorily. The subcontractor must agree to comply with all applicable Medicaid laws, regulations, subregulatory guidance, and contract provisions and permit the state or federal government to audit to the same extent those entities are permitted to audit Plans.

The final rule also applies these provisions to Child Health Plus.

B. Program Integrity

1. Provider Screening Requirements

Beginning with contract periods that are effective on or after July 1, 2018, states must screen, enroll, and revalidate all Plan network providers. Plan providers are not required to participate with FFS Medicaid pursuant to this requirement. However, CMS believes that a significant number of Plan providers have already been screened pursuant to their participation with states' Medicaid programs or Medicare FFS (states can rely on Medicare screening for Medicaid purposes). CMS acknowledges that states may delegate functions such as screening to Plans but is concerned about quality control, consistency, and duplication of efforts and the ability of Plans to conduct functions such as fingerprint background checks for high risk providers. To mitigate concerns regarding delays caused by this screening process, CMS permits Plans to contract with providers during the screening process for up to 120 days. If the provider is denied or terminated, or upon the expiration of the 120 days, the Plan must terminate the contract. Notably, if a provider is later found to have been excluded or sanctioned during the 120 days, the Plan would not be insulated from penalties associated with payments for services. In response to comments, CMS clarifies that consumer directed assistants are also subject to the screening and enrollment requirements. For Medicaid-only providers, states must assign the appropriate risk level and perform the requisite screenings. Finally, out-of-network providers under a single case agreement are not network providers and are therefore exempt from the screening requirements.

States are also required to review the ownership and control information for all Plans and Plans' subcontractors, and confirm the identify and exclusion status of the entities and any individuals with ownership and control interest or who is an agent or managing employee through routine checks of federal databases at least monthly.

States must ensure that Plans are not located outside the United States and that no payments are made for services or items to any entity or financial institution outside the U.S. However, payment for tasks that support administration may be made to financial institutions located outside the U.S..

2. Integrity Audits

At least once every three years, states are required to conduct an independent audit of the accuracy, truthfulness, and completeness of encounter and financial data submitted by Plans. States must post to their websites or otherwise make available the Plan contracts, documentation on availability and accessibility of services, ownership and control information, and results of encounter and financial audits. Data, documentation, and information submitted by Plans must be certified at each submission by the Plans' chief executive officers or chief financial officers or their designees based on best information, knowledge, and belief, although CMS expects Plans to undertake "reasonably diligent review of the data, documentation, and information."

Plans and subcontractors, to the extent subcontractors provide coverage for services and payment of claims, must implement and maintain arrangements and procedures to detect fraud, waste, and abuse, including:

- Written policies and procedures and standards of conduct that articulate the Plan's commitment to comply with applicable requirements;
- Designation of a Compliance Officer who reports directly to the chief executive officer, or other executive level position, and the board of directors;
- A Regulatory Compliance Committee on the board of directors and senior management level charged with overseeing the compliance program;
- A system for training and education for the Compliance Officer, senior management, and employees,
- Effective lines of communication between the Compliance Officer and employees;
- Enforcement of standards through disciplinary guidelines; and
- Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues, investigation of potential compliance problems, and correction of problems. This includes coordinating with state program integrity officials and law enforcement agencies.

3. Reporting and Referrals

Plans must have procedures for prompt reporting of all improper payments and prompt notification when they receive information impacting a member's eligibility such as a change in residence or income or the death of the enrollee. State notification is required when there has been a change in a network provider's circumstances impacting the provider's eligibility to participate in managed care, including termination of the provider's agreement. Plans must have a method for verifying that services billed by providers were received by members and must have written policies related to the Federal False Claims Act, including information about the rights of employees to be protected as whistleblowers.

Plans must refer any potential fraud, waste, or abuse to the state program integrity unit or potential fraud to the state Medicaid Fraud Control Unit (MFCU) and the program integrity unit. In response to questions regarding the definition of potential fraud, CMS clarifies that potential fraud is conduct that the Plan believes is fraud—a determination as to whether conduct is actually fraud can only be made by law enforcement and the courts. If suspected fraud has been investigated by the Plan's special investigation unit, the state's program integrity unit should try to avoid duplication of the preliminary investigation. Plans must also report overpayment recoveries.

Plans must suspend payments to network providers upon notice from the state of an investigation pursuant to credible evidence of fraud unless the state determines there is good reason not to suspend such payments.

5. Disclosures

Plans are required to disclose any relationships with debarred individuals or providers, ownership and control information, and report within 60 calendar days when payments in excess of amounts specified in the contract have been identified.

6. Overpayment Recoveries

Contracts with Plans must specify:

- the retention policies for the treatment of recoveries from Plan providers due to fraud, waste, or abuse;
- the process, timeframes, and documentation required for reporting the recovery of all overpayments; and
- the process, timeframes, and documentation for payment of recoveries of overpayments to the state in situations where the Plan is not permitted to retain some or all of the recovered overpayments.

CMS states that it believes "the ability of managed care plans to retain overpayments that they identified and recovered is a reasonable mechanism to incentivize managed care plans to oversee the billing practices of network providers."

Plans must have a mechanism for providers to report overpayments and return overpayments within 60 days of the date on which the overpayment was identified. Plans must report overpayment recoveries to the state at least annually and the state must use the information in setting actuarially sound capitation rates.

7. Prohibited Affiliations

Plans may not have prohibited relationships with individuals or entities convicted of fraud against Medicare, Medicaid, or CHP, patient abuse, health care fraud, or drug charges related to controlled substances. The prohibition applies whether or not the relationship is known to the Plan and is applicable to:

- directors, officers, or partners of the Plan;
- subcontractors;
- a person with a beneficial ownership of 5% or more in the Plan; or
- a network provider or person with an employment, consulting, or other arrangement with the Plan for the provision of items and services that are significant and material to the Plan's obligations under its contract with the state.

8. Sanctions

CMS clarified the requirements for intermediate sanctions by indicating that states *may* use the specified intermediate sanctions but are not required to do so. Contracts must continue to include a provision providing states the authority to impose intermediate sanctions. States are also required to have the authority to appoint temporary management. Intermediate sanctions may be imposed in the following circumstances:

- Plan fails to substantially provide medically necessary services when required to do so for an enrollee covered under the contract;

- Plan imposes premiums or charges in excess of those permitted;
- Plan acts to discriminate among enrollees on the basis of health state or need for services;
- Plan misrepresents or falsifies information furnished to CMS, the state, enrollee, potential enrollee, or health care provider;
- Plan fails to comply with the requirements for physician incentive plans; and
- Plan distributes marketing materials that have not been approved by the state or that contain false or materially misleading information.

Compliance with these program integrity provisions is not required until the rating period beginning on or after July 1, 2018

The final rule also applies the Program Integrity provisions to Child Health Plus.

VI. APPEALS/GRIEVANCES

The regulation makes a number of changes to align the MMC appeal and grievance provisions with those of Medicare Advantage plans and private insurance. CMS correctly recognizes that different appeal and grievance processes by line of business create operational burdens on Plans and confusion among consumers.

A. General Changes

To remove any ambiguity, the regulation clarifies that the duration of time frames related to grievances and appeals are calendar days.

B. Definitions

The regulation replaces the word “action” with “adverse benefit determination” to lay the foundation for Plans to use consistent processes across programs. The definition of “adverse benefit determination” will include the existing definition of “action.” Thus, “adverse benefit determination” will mean:

- The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit;
- The reduction, suspension, or termination of a previously authorized service;
- The denial, in whole or in part, of payment for a service;
- The failure to provide services in a timely manner;
- The failure of a Plan to act within the timeframes regarding the standard resolution of grievances and appeals;
- For a resident of a rural area with only one Plan, the denial of an enrollee's request to exercise his or her right to obtain services outside the network;
- The denial of an enrollee’s request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

"Appeal" means a review by a Plan of an adverse benefit determination. "Grievance" means an expression of dissatisfaction about any matter other than an adverse benefit determination. Despite the agencies' attempt to align definitions across markets, there is still a disconnect with New York's grievance and appeal process. For commercial Plans in New York, a grievance relates to benefit denials that are not based on medical necessity. Thus, there will still be separate processes and definitions in place in New York with respect to commercial and Medicaid Plans.

The regulation also adds a definition of "grievance and appeal system," which is defined as the processes Plans implement to handle appeals and grievances and collect and track information about them.

C. Grievance/Appeal Process Structure

The regulation limits enrollees to one level of appeal before exhausting a Plan's internal appeal process. Once this single level of appeal is exhausted, but not before, the enrollee is able to request a Fair Hearing. This results in a significant change in the way appeals are handled in New York. Currently, enrollees are able to request a Fair Hearing whenever an action is taken (i.e., prior to exhaustion of the internal appeal process). By requesting a Fair Hearing, enrollees are eligible for aid continuing. Under the final rule, aid continuing is available from the time of the initial determination through the conclusion of the Fair Hearing. This will likely result in Plans paying for aid continuing for a substantially longer period of time. Although the regulation allows states to permit Plans to recoup money for services from enrollees in the event coverage is ultimately denied, states would have to follow the same process for both FFS and MMC. Additionally, the likelihood of Plans being able to recoup this money from enrollees is extremely low.

D. Adverse Benefit Determination Timeframes and Notices

Notices of adverse benefit determinations will largely follow the existing requirements for notices of actions, with changes to reflect revisions made elsewhere in the regulation. Additionally, the reason for the determination must now include the right of the enrollee to request free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's claim for benefits. This additional documentation includes information regarding medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

The final regulation adds a requirement that the adverse benefit determination notice include information on the right to appeal the adverse determination, including information on exhausting the single level of appeal and the right to request a Fair Hearing.

E. Handling of Grievances and Appeals

The final regulation does not remove the requirement for a provider to obtain an enrollee's written consent in order to submit an appeal on the enrollee's behalf, as had been proposed.

Despite requests to remove the requirement that enrollees follow standard oral appeals up with a written appeal, the agencies declined to do so. The preamble to the regulation does clarify, however, that the resolution timeframe begins from the date of the oral appeal, and not the written appeal.

Currently, states can choose to require appeals to be filed anywhere between 20 and 90 days from receipt of an adverse determination. The regulation deletes this provision and requires appeals to be filed within 60 days of the date of the notice of an adverse benefit determination. New York currently allows plans to choose whether to allow 60 days or 90 days to file an appeal, so only those plans that allow 90 days must revise this timeframe.

The regulation does not impose any time limit on filing a grievance.
Consistent with commercial insurance, the regulation adds a requirement that the individual reviewing a grievance or appeal cannot be the subordinate of an individual involved in any previous level of the review. It also requires reviewers to take all comments, documents, records, and other information submitted by the enrollee into account regardless of whether the information had been considered in the initial review.

Under the existing regulation, enrollees can review their case file "before and during" the appeal process. The regulation revises this to clarify that enrollees can review their files "sufficiently in advance of the resolution." It also clarifies that in addition to the case file, individuals can review any "new or additional evidence."

F. Resolutions of Grievances and Appeals

The regulation makes significant modifications to the resolution and notice provisions to align with commercial insurance. First, the regulation changes the timeframe for determining appeals. (Note that time timeframes for determining grievances are unchanged.) Currently, Plans have up to 45 days to make a determination on a standard appeal. The regulation changes this to 30 days. This will not be a change for Plans in New York as they are already required to determine internal appeals within 30 days. For expedited appeals, Plans currently have 3 business days to make a determination. The regulation changes this to 72 hours, which is consistent with commercial insurance requirements under the Department of Labor regulations. This will require changes by New York Plans.

The regulation strengthens the notice requirements that apply when a Plan needs an extension of time to make a determination on a grievance or appeal. Specifically, it requires written notice within two days of the reason for the extension and of the enrollee's right to file a grievance if he/she disagrees with the extension. It also requires Plans to make reasonable efforts to give enrollees prompt oral notice of the extension. The regulation adds a requirement that grievance and appeal notices must provide meaningful access for individuals with disabilities and limited English proficient individuals by meeting the standards required of other enrollee materials. (See section X.)

G. External Appeal

In response to comments on the proposed regulation, the final regulation permits states to offer enrollees the option of an external medical review. The review must be at the enrollee's option and must not be a requirement before, or used as a deterrent to, proceeding to the Fair Hearing. Further, the review must be independent of both the state and the Plan, it must be offered without any cost to the enrollee, and it must not extend any of the timeframes for making appeal determinations and must not disrupt the continuation of benefits. Since New York already permits enrollees to file an external appeal, this will not impact Plans in New York.

H. Fair Hearings

The regulation lengthens the timeframe to request a Fair Hearing from 60 days (which is the rule in New York) to 120 days.
As mentioned above, the regulation requires enrollees to exhaust the internal appeal process before requesting a Fair Hearing. However, an enrollee will be deemed to have exhausted the internal appeal process if the Plan fails to adhere to the notice and timing requirements regarding appeal determinations. This will result in a change for New York Plans, as enrollees can currently request a Fair Hearing at the same time as an internal appeal.

I. Recordkeeping Requirements

The regulation sets minimum standards for the types of information that must be collected. The following information must be kept in each record of a grievance or appeal: a description of the reason for the appeal or grievance, the date received, the date of each review or review meeting if applicable, the resolution at each level, the date of resolution, and the name of the enrollee involved. The record must be accurately maintained and available for inspection by the state and CMS.

J. Reversed Appeals

The regulation requires Plans to effectuate a reversal of an adverse benefit determination and authorize or provide such services no later than 72 hours from the date they receive notice of the adverse benefit determination being overturned. This is a change from the current standard that requires Plans to provide services "promptly, and as expeditiously as the enrollee's health condition requires."

The final regulation applies the Medicaid grievance and appeal provisions to Child Health Plus, except for the aid continuing and Fair Hearing provisions.

VII. BENEFICIARY PROTECTIONS

A. Enrollment

The regulation addresses what it refers to as a gap in the regulation regarding MMC enrollment. The preamble explains that there are currently no regulatory provisions for the enrollment of

individuals in MMC, other than the default enrollment provisions. As a result, states have established a variety of approaches to enrolling individuals into voluntary and mandatory MMC.

Significantly, CMS did not finalize the proposed provision that would have required states to provide at least 14 days of FFS coverage during which enrollees could make an active choice of their MMC plan. Thus, New York can continue to use its current process of allowing individuals to choose a Plan upon enrollment, and if no Plan is chosen, enrolling the individual in FFS until an auto assignment is made.

The regulation requires states to develop informational notices to ensure that beneficiaries are fully aware of the implications of not selecting a plan and of allowing auto assignment to occur. The notice must explain the process for enrolling in a Plan, including the choice of Plans available, how to make the enrollee's selection of a Plan known to the state, and the enrollee's right to disenroll within 90 days from the effective date of the enrollment. The notice must also include contact information for the state's beneficiary support system (explained below). The information notice must be provided at the time an individual becomes eligible for enrollment and within a timeframe that allows the individual to use the information to choose a Plan.

With respect to auto assignment processes, the regulation provides that if a state cannot preserve existing provider-patient relationships when auto assigning enrollees to Plans, then enrollees must be "equitably distributed." This means that the criteria applied to make default enrollments must be fair and reasonable and that the pool of Plans eligible to receive default enrollments is not based on arbitrary criteria. States also have flexibility to use additional criteria when making default assignments, such as the geographic location of the enrollee, enrollment preferences of family members, previous plan assignment of the enrollee, quality assurance and improvement performance, procurement evaluation elements, and other reasonable criteria that support the goals of the Medicaid program.

B. Disenrollment Standards

Enrollees currently have a 90 day period to disenroll from a Plan without cause. This means that enrollees can continually switch Plans within 90 days. The proposed regulation would have revised this provision by limiting the 90 day disenrollment period to an enrollee's initial enrollment into any Plan. In other words, an individual could only exercise the 90 day disenrollment right one time, upon initial enrollment in a Plan. The final rule does not make this revision. Thus, each time an enrollee enrolls in a new Plan, he/she will be able to disenroll within 90 days. The preamble to the regulation also clarifies that states can choose to provide a period of more than 90 days to disenroll.

With respect to the requirement that enrollees have the opportunity to switch Plans every 12 months without cause, the preamble notes that states can choose to run the 12 month period from the initial date of enrollment or from the end of the initial 90 day enrollment period; New York begins the 12 months from the initial date of enrollment. The preamble also clarifies that states can provide more than one period within 12 months in which enrollees can disenroll without cause.

As proposed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment.

The regulation clarifies that states can choose how to allow disenrollments to occur. That is, they can allow enrollees to disenroll orally or in writing (including electronically), or both. States must clearly communicate to enrollees the manner in which they can disenroll.

The regulation also adds a new reason that enrollees may disenroll from a Plan for cause. Specifically, enrollees can disenroll if a residential, institutional, or employment supports provider leaves the Plan's network and the enrollee loses his/residence or employment as a result. We do not anticipate that this would be a significant change in New York given DOH's liberal approach to allowing disenrollments. (This provision does not apply until the first rating period on or after July 1, 2017.)

The final regulation also applies these disenrollment provisions to Child Health Plus, except the provisions regarding Fair Hearings.

C. Beneficiary Support System

The regulation includes a new provision that requires states to implement a beneficiary support system to provide support before and after enrollment in a Plan. Such beneficiary support systems will be required to:

- ensure that choice counseling is made available to all enrollees;
- provide assistance to all beneficiaries in understanding managed care; and
- provide assistance for enrollees who receive or desire to receive LTSS.

The beneficiary support system would have to be available in person, by phone, and via the internet. "Choice counseling" is defined as "the provision of information and services designed to assist beneficiaries in making enrollment decisions," including answering questions and identifying factors to consider when choosing among Plans and primary care providers. Counseling must be available prior to enrollment and when enrollees can or must change enrollment. Although the regulation gives states flexibility with respect to who can provide choice counseling, the regulation provides that entities providing choice counseling are considered enrollment brokers and must meet the conflict of interest provisions related to those entities, which include not having a financial relationship with any Plan.

The regulation includes four additional requirements for beneficiary support systems specific to beneficiaries who use LTSS. Such systems must provide:

- An access point for complaints and concerns about enrollment, access to covered services, and other related matters;
- education on enrollees' grievance and appeal rights, the state fair hearing process, and rights and responsibilities;
- assistance, upon request, in navigating the grievance and appeal process and appealing adverse benefit determinations made by a Plan to a state fair hearing; and

- review and oversight of LTSS program data to assist the state Medicaid Agency on identification and resolution of systemic issues

In order for a state to claim Federal Financial Participation for LTSS beneficiary support system services, costs must be supported by an allocation methodology that appears in the state's Public Assistance Cost Allocation Plan; the costs must not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs; the person or entity providing the service must meet independence and conflict of interest provisions applicable to enrollment brokers; and the initial contract or agreement for services must be reviewed and approved by CMS.

The preamble explains that the regulation does not intend for states that already provide such supports to rebuild their systems, but rather that they draw upon or expand their systems to meet the new standards. New York currently utilizes the services of an enrollment broker to provide education before and after enrollment in managed care. This enrollment broker could be used to provide choice counseling services required under the regulation. In addition, pursuant to funding made available through the Balance Incentive Program, New York has contracted with a long term care ombudsman to provide services required for individuals in receipt of long term services and supports. The preamble makes clear that the beneficiary support system is distinct from the long term care ombudsman program, so New York will be required to enhance its existing systems to meet the new standards.

These provisions do not apply until the first rating period on or after July 1, 2017.

D. Utilization Review Standards

1. General

The preamble states that current standards reflect care for acute care conditions, and not chronic, long-term conditions which are becoming an increasing part of the MMC program. The regulations make changes to utilization review standards to ensure that individuals with chronic conditions receive the long-term services and supports they need. Currently, the general rule for Medicaid services is that they must be sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished, and services must not be arbitrarily denied or reduced because of the diagnosis or condition of the enrollee. The regulation removes the words "be expected to" from this definition, such that services would have to "reasonably achieve" the purpose for which the services are furnished. Additionally, with respect to the requirement that services be provided in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid, the final rule applies the same standard to enrollees under the age of 21, to address EPSDT requirements. The rule makes this change instead of revising the definition of medical necessity to specify that the criteria used to determine medical necessity must meet the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found (EPSDT), as had been proposed.

State contracts with Plans must also specify what constitutes medically necessary services by addressing the extent to which the Plan is responsible for covering services that address "the prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability." Additionally, medical necessity criteria must address the opportunity for enrollees to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

As proposed, the regulation also requires Plans to authorize clinical services that support individuals with ongoing or chronic conditions, as well as LTSS, in a manner that reflects the enrollee's continual need for such services and supports. CMS expects states to monitor Plans' compliance with setting reasonable authorization periods and imposes state monitoring standards.

The regulation also finalizes the proposal that a Plan's utilization review criteria not interfere with enrollees' freedom to choose a method of family planning. This provision does not preclude Plans from applying medical necessity criteria to an enrollee's request for family planning services, but prohibits controls that would interfere with an enrollee's freedom to choose the method of family planning (e.g., by requiring a different method to be tried first).

2. Authorizations

The regulation requires Plans to authorize LTSSs based on an enrollee's current needs assessment and consistent with the person-centered service plan.

The regulation changes the timeframe within which expedited preauthorization determinations must be made from 3 business days to 72 hours. This will align the timeframes for making other expedited benefit determinations and expedited appeal determinations.

The final regulation also applies these provisions to Child Health Plus, except for the provisions relating to what constitutes a medical necessity denial and the LTSS provisions. This will result in a significant change for Child Health Plus.

Compliance with these provisions is required beginning with the first rating period on or after July 1, 2017.

E. Aid Continuing

As proposed, the final rule eliminates the requirement that an individual request a Fair Hearing in order to receive aid continuing. Rather, an enrollee is eligible to continue receiving services through the duration of a Fair Hearing, as long as:

- The enrollee timely files a request for an appeal;
- The appeal involves the termination, suspension, or reduction of previously authorized services;
- The services were ordered by an authorized provider;
- The period covered by the original authorization has not expired; and

- The enrollee requests aid continuing on or before the later of (i) within 10 calendar days of the Plan sending the notice of adverse benefit determination; or (ii) the intended effective date of the Plan's adverse benefit determination. Thus, for example, if an enrollee's services are authorized until the 30th of the month, and the Plan does not send the adverse benefit determination until the 29th, the enrollee has until the 9th of the following month to request aid continuing.

The preamble acknowledges that a request for aid continuing may be received before a request for an appeal, but confirms that actual aid continuing is contingent upon the timely filing of an appeal. The preamble encourages Plans to specify in their adverse determination notices that requests for aid continuing and an appeal may be filed together.

With respect to the duration of aid continuing, the regulation provides that benefits must continue until:

- The enrollee withdraws the appeal or request for a Fair Hearing; or
- The enrollee fails to request a Fair Hearing and aid continuing within 10 days after the Plan sends an adverse appeal determination notice to the enrollee; or
- The enrollee receives an adverse decision on the Fair Hearing

If a Plan's adverse determination is upheld on appeal, the Plan can recover the cost of the services provided as aid continuing if the state permits the Plan to do so (and the Plan is able to collect from the enrollee).

Compliance with these provisions is required beginning with the first rating period on or after July 1, 2017.

F. Transitional Care

The regulation requires states to have a transition of care policy in place when an enrollee moves from FFS to MMC or from one MMC Plan to another if the enrollee would experience serious detriment to his/her health or put him/her at risk of hospitalization without continued services. Such transition of care policies would have to:

- Permit the enrollee to continue to receive the services they are currently receiving from their current provider for a specified period of time;
- Refer the enrollee to an appropriate participating provider;
- Assure that the state or former MMC Plan complies with requests for historical utilization data; and
- Assure that the enrollee's new provider is able to obtain appropriate medical records

States' transition of care policies would have to be included in contracts with Plans. We do not think these standards differ materially from the transition of care requirements currently applicable to Plans in New York.

Compliance with these provisions is not required until the first rating period on or after July 1, 2018.

The final regulation also applies these provisions to Child Health Plus.

G. Care Coordination

1. Generally

The regulation expands the current care coordination provisions by requiring Plans to formally designate a person or entity as the care coordinator for each enrollee. Contact information for the care coordinator must be given to each enrollee.

Additionally, Plans must coordinate services across care settings, coordinate services provided outside of the Plan, including other Plans and FFS, and coordinate services enrollees receive from community and social support providers.

The regulation requires each Plan to make its best effort to complete an initial health screening within 90 days of the effective date of enrollment for all new enrollees. If an initial attempt to contact an enrollee for completion of the screening is unsuccessful, the Plan must make another attempt to contact the enrollee.

Plans' care coordination procedures must also ensure that all providers, practitioners, and suppliers maintain and share an enrollee health record in accordance with professional standards. The preamble notes that Plans' contracts with providers should include this requirement in order for Plans' to comply with this provision.

The final regulation also applies these provisions to Child Health Plus.

2. LTSS

Currently, regulations require states to have mechanisms in place to identify individuals with special needs to Plans. The regulation adds to this by requiring states to also identify individuals needing LTSS to Plans. These mechanisms must be included in states' comprehensive quality strategies.

The existing provisions regarding additional services for enrollees with special health care needs are also revised to:

- require Plans to conduct comprehensive assessments of individuals identified by the state as being in need of LTSS, as well as those with special health care needs, with the assessments being conducted by LTSS service coordinators having qualifications specified by the state or the Plan, or by appropriate providers.

- clarify that treatment plans are also considered service plans and that they must be developed for individuals needing LTSS, and for those with special health care

needs determined to need a course of treatment or regular monitoring, if required by a state.

- require that treatment or service plans be developed by an individual meeting the Plan's or state's standard for providing service coordination (including internal staff), in consultation with providers caring for the enrollee.

- require that treatment or service plans developed for those in need of LTSS conform with the person centered planning standards found in other provisions of the rule

- require service and treatment plans to be reviewed and revised upon reassessment of the enrollee's functional needs, at least every 12 months, when the enrollee's circumstances or needs change significantly, or at the request of the enrollee.

This section applies to rating periods for contracts with Plans beginning on and after July 1, 2017.

H. Managed Long Term Care Services and Supports

As used in the regulation, managed long term care services and supports ("MLTSS") refers to an arrangement between state Medicaid programs and Plans through which the Plan receives a capitated payment for providing long term services and supports (LTSS).

The regulation defines LTSS as "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 worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting." The definition includes community based services, which are non-medical in nature and focused on functionally supporting people living in the community, such as personal care services.

The regulation includes the following standards for MLTSS programs, which were previously issued in connection with MLTSS waiver programs:

1. Adequate Planning – The regulation addresses this standard by requiring that, as with all managed care programs, there is appropriate state monitoring and accountability of the program that includes readiness reviews. The regulation also addresses this standard by proposing additional standards for enrollee and prospective enrollee materials that apply to all programs, including information on transition of care, who to contact for support, and other standards for provider directories. (See section X below.)

2. Stakeholder Engagement – The regulation requires states to create and maintain stakeholder groups with respect to the design, implementation, and oversight of the MLTSS program. The groups must include enrollees, representatives of enrollees,

providers, and other stakeholders. The frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.

In addition to state stakeholder groups, each Plan that provides LTSS must maintain a member advisory committee comprised of a reasonably representative sample of the covered LTSS populations or other individuals representing those enrollees to solicit direct input on the enrollees' experiences.

3. Enhanced Provision of Home and Community Based Services

4. Alignment of Payment Structures and Goals – The regulation addresses this by requiring states to include MLTSS program elements in the annual program summary report. (See section IX.E below.)

5. Support for Beneficiaries –The regulation addresses this standard by requiring states to provide a beneficiary support system, including choice counseling services, as discussed above in section VII.C above. The new "for cause" disenrollment reason referenced above with respect to a residential, institutional, or employment supports provider leaving a Plan's network also addresses this standard. Lastly, as discussed above, the regulation describes the conditions that must be met for the state to claim FFP for the LTSS-specific beneficiary support system activities.

6. Person-centered Processes – This standard is met by requiring the identification, assessment, and treatment/service planning for individuals receiving LTSS who are enrolled in a Plan, as discussed above in section VII.C.

7. Comprehensive, Integrated Service Package – This standard is met by the care coordination provisions of the regulation discussed above in paragraph VII.G.

8. Qualified Providers - CMS meets this standard by requiring states to establish time and distance standards specifically for MLTSS programs, as well as accessibility standards and credentialing and re-credentialing standards for all provider types. (See paragraph VIII below.)

9. Participant Protections and Quality - States will have to include provisions in contracts with Plans that require Plans to participate in state efforts to prevent, detect, and remediate all critical incidents. The state contract must specify Plans' roles and responsibilities with respect to these events. The regulation also requires quality systems to have MLTSS-specific elements. (See paragraph VII.C above.)

These provisions do not apply until the first rating period on or after July 1, 2017.

VIII. NETWORK ADEQUACY STANDARDS

Compliance with these provisions is not required until the first rating period beginning on or after July 1, 2018.

CMS notes that there is currently wide variation in how states define adequate networks and how frequently networks are reviewed. As a result, the regulation imposes new minimum standards for networks.

Rather than CMS setting specific time and distance standards, the rule requires states to set their own time and distance standards for primary care (adult and pediatric), OB/GYN, behavioral health (mental health and substance use disorder, as well as adult and pediatric), specialist (adult and pediatric), hospital, pharmacy, and pediatric dental providers that reflect the geographic scope of the program. New York already imposes time and distance standards for most provider types. In developing network adequacy standards, states must consider:

- anticipated Medicaid enrollment;
- expected utilization of services;
- 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;
- the geographic location and accessibility of the providers and enrollees, considering
- distance, travel time, the means of transportation ordinarily used by Medicaid enrollees;
- the ability of network providers to communicate with limited English proficient enrollees in their preferred language;
- the ability of network providers to ensure physical access, reasonable accommodations,
- culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities; and
- the availability of triage lines or screening systems, as well as the use of telemedicine, evisits, and/or other evolving and innovative technological solutions.

If states permit exceptions to the time and distance standards, the standards for granting exceptions must be specified in the contract and must be based on the number of providers practicing in an area. States must monitor enrollee access under exceptions and report this information to CMS.
States' network adequacy standards must be posted on the states' websites. The standards must also be available at no charge upon request to individuals with disabilities in alternate formats.

The regulation also imposes minimum standards for how states adopt network adequacy standards to ensure the availability of critical services and supports for MLTSS beneficiaries. States must consider the same standards as set forth above when setting time and distance standards, as well as the ability of an enrollee to choose a provider, and strategies to support community integration of LTSS enrollees. States must also set standards other than time and distance standards for LTSS provider types that travel to enrollees' homes. For example, the preamble states that assessing network adequacy for individuals receiving care in the home may be based on enrollee-to-provider ratios.

The regulation requires Plans to submit network data to states annually, and states to certify compliance to CMS annually by submitting documentation of the state's analysis supporting certification of the Plan's network. This is in addition to the requirement to submit this data

when there has been a significant change in a Plan's operations that affect capacity and services, such as a significant change in the composition of the Plan's network.

With respect to accessibility, the regulation clarifies that services are to be made available and accessible in a timely manner and requires Plans to participate in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. It also emphasizes the need for providers to have the capabilities to ensure physical access, accommodations, and accessible equipment for the furnishing of services to Medicaid enrollees with physical or mental disabilities. Lastly, the regulation requires states to include a contract provision in all contracts requiring Plans to demonstrate that they have sufficient providers for family planning services in network to provide timely access.

The final regulation also applies these provisions to Child Health Plus.

IX. QUALITY OF CARE PROVISIONS

A. Quality Assessment and Performance Improvement Programs

Existing regulations require states to require Plans to establish and implement quality improvement and performance improvement programs ("QAPIPs") that include various provisions and measures. The final regulation adds additional specifications for Plans providing LTSS. Specifically, QAPIPs of Plans providing LTSS must include:

1. Mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS, including assessment of care between care settings and a comparison of services and supports received with those set forth in the enrollee's treatment/service plan, if applicable; and

2. Participation in efforts by the state to prevent, detect, and remediate critical incidents that are based, at a minimum, on the requirements on the state for home and community based waiver programs.

As finalized, the rule allows CMS to specify quality measures and performance improvement project topics for managed care programs. States may continue to adopt state-specific measures and projects. National measures and project topics chosen by CMS will be subject to a public notice and comment before being finalized. States may request a waiver from the CMS measures and PIP topics. CMS intends to issue future guidance regarding the waiver process.

For LTSS, the regulation requires Plans to report on measures that asses the care received by beneficiaries transitioning service settings and the experience of care. CMS also requires review and reporting on the services included in care plans to be compared to the services received by beneficiaries. States with a self-direction option such as New York are encouraged to include measures specific to self-direction.

In New York, mainstream managed care plans already report on Quality Assurance Reporting Requirements (QARR) measures which are largely taken from the Healthcare Effectiveness Data and Information Set (HEDIS) data with some state-specific measures included and Plans covering LTSS are subject to LTSS specific measures taken largely from the SAAM and its replacement, the UAS-NY. Additionally, DOH conducts CAHPs surveys to measure experience and satisfaction with care. As finalized, the regulation may lead to additional or changed measures to be included in QARR. With respect to PIPs, New York Plans are already required to complete PIPs that are coordinated by the DOH. Therefore, it appears that the impact of the rule on PIPs will be limited.

CMS did not finalize its proposal that would have required that Plans be subject to a performance-based review prior to contracting with states to participate in managed care. As finalized, the regulation simply requires states to confirm the accreditation status of Plans at least once per year, to require their Plans to authorize the release of the most recent accreditation review to the state, and to post and update the accreditation status of Plans at least annually.

These provisions will not apply until the first rating period on or after July 1, 2017.

The final regulation also applies these provisions to Child Health Plus.

B. Quality Rating System

The final rule provides that CMS will create a new Plan quality rating system (QRS) after a public notice and comment period. The MMC QRS will align with the QHP summary indicators (clinical quality management; member experience; and plan efficiency, affordability, and management).

CMS will work with states and stakeholders to determine a standardized set of plan performance measures that will form the basis for the star ratings. The preamble notes that each state's MMC QRS will use state level data that will provide comparisons across Plans within a state. States will be required to issue quality ratings annually and post the ratings on their websites.

The final rule allows states to adopt an alternative MMC QRS upon approval by CMS, provided that the ratings generated by the alternative MMC QRS yield substantially comparable information regarding Plan performance to that yielded by the CMS-developed MMC QRS. States seeking an alternative QRS must provide an opportunity for public comment of at least 30 days and obtain the input of the state's Medicaid Medical Care Advisory Committee. Requests for alternative QRS must document the public comment process utilized by the state including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must also document any policy revisions or modifications made in response to the comments and rationale for comments not accepted. New York will likely seek approval of its existing QRS. CMS will issue guidance in the future regarding requests for approval of alternative QRS.

States will not be required to adopt a QRS until approximately 2021 - three years after CMS issues guidance specifying the measures and methodologies for the MMC QRS.

The final rule also applies these provisions to Child Health Plus.

C. State Quality Strategy

States operating Medicaid managed care programs are currently required to draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by Plans. The proposed regulation would have added a new requirement that states develop a comprehensive quality strategy for all Medicaid programs, including fee for service. CMS chose not to finalize this provision, noting that it would have imposed significant logistical and resource challenges for states.

The final regulation revises the current requirements for states to have written quality strategies. Specifically, the regulation requires quality strategies to include:

1. Network adequacy and availability of services standards for MCOs and examples of evidence-based clinical practice guidelines the state requires;

2. The state's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the state served by the Plan;

3. A description of the quality metrics and performance targets to be used in measuring the performance and improvement of each Plan, including but not limited to, the performance measures required by the state with respect to QAPIPs. The state must identify which quality measures and performance outcomes the state will use and the performance improvement projects to be implemented, including a description of any interventions the state proposes to improve access, quality, or timeliness of care for beneficiaries;

4. Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each Plan;

5. A description of the state's transition of care policy;

6. The state's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. States must identify this demographic information for each Medicaid enrollee and provide it at the time of enrollment;

7. Appropriate use of intermediate sanctions;

8. The mechanisms implemented by the state to identify persons who need LTSS or persons with special health care needs.

States must make their quality strategies available for public comment and obtain input from the Medical Care Advisory Committee before submitting the strategy to CMS for review. The

quality strategy must be reviewed and updated at least every three years and whenever there is a significant change and must be posted on the state's website.

CMS intends to issue a toolkit for states to use in developing their quality strategies. New York already publishes an extensive Quality Strategy that includes information on every managed care program operated by the state and is updated by DOH every two years. New York will need to update its strategy to incorporate elements newly required under the regulation. Any changes that are required must be made by July 1, 2018.

The final regulation also applies these provisions to Child Health Plus.

D. External Quality Review

The final rule largely leaves existing requirements for External Quality Reviews ("EQR") intact, but makes several changes. Preliminarily, it revises several definitions related to EQRs. It changes the definition of "quality" to reflect that professional knowledge must be evidence-based and supported by current science, and to include performance measure trends and performance improvement outcomes. Thus, "quality" for purposes of EQR means the degree to which a Plan increases the likelihood of desired outcomes by "(1) Its structural and operational characteristics. (2) The provision of services that are consistent with current professional, evidenced based-knowledge. (3) Interventions for performance improvement." The preamble notes that "interventions for performance improvement" could include considerations around quality of life for individuals receiving LTSS. To clarify that the EQR provisions apply to LTSS, the final regulation also adds definitions of "health care services" and "outcomes" that encompass these services.

Additionally, under the final regulation, network adequacy is added to the list of standards that must be evaluated as part of an EQR. CMS envisions that as part of the EQR, direct testing of the accuracy of network information through telephone calls to provider offices to test wait times and the accuracy of provider information would occur. The preamble notes that states that have existing network adequacy review methodologies in place will have the opportunity to demonstrate how they are consistent with EQR protocols. New York currently uses an external vendor to secret shop for appointment availability as well as the accuracy of provider information contained in provider directories. We expect that the DOH will be able to continue to use this process under the final regulation.

The final regulation allows states to use information from the Medicare program or a private accreditation entity for the validation of PIPs and performance measures and for the compliance review as long as the standards for that review are comparable to the standards for the EQR-related activities, consistent with the EQR protocols. New York views its standards as superior to private accrediting agencies and is unlikely to take advantage of this new flexibility under its existing regulatory scheme.

Finally, the regulation makes several changes to the requirements related to EQR results. First, EQR technical report must include performance measurement data for any collected performance measures and implemented PIPs. Also, the report must include recommendations for how states

can target the goals and objectives in the comprehensive quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries. Only qualified EQR organizations can complete the technical report and it must be completed and available for public consumption no later than April 30th of each year. The final report must be posted on the state's website.

Compliance with these provisions is not required until July 1, 2018.

The final regulation also applies these provisions to Child Health Plus, except that states are not permitted to use Medicare accreditation as a substitute for EQR activities.

E. State Monitoring Standards

The final rule requires states to have monitoring systems for managed care programs that include oversight of at least the following: administration and management; appeals and grievances; claims management; enrollee materials and customer services, including beneficiary support system activities; finance, including MLR reporting; information systems, including encounter data reporting; encounter data reporting; marketing; utilization management; program integrity; provider network management, including provider directory standards; availability and accessibility of services, including network adequacy standards; quality improvement; and delivery of LTSS. The only item that will be new for New York is MLR reporting as discussed in other sections of this memorandum.

States must collect and use the following data as part of their monitoring activities:

1. Enrollment and disenrollment trends in each MCO;
2. Member grievance and appeal logs;
3. Provider complaint and appeal logs;
4. Findings from the state's EQR process;
5. Results from any enrollee or provider satisfaction survey conducted by the state or MCO;
6. Performance on required quality measures;
7. Medical management committee reports and minutes;
8. The annual quality improvement plan for each MCO;
9. Audited financial and encounter data submitted by each MCO;
10. MLR summary reports;
11. Customer service performance data submitted by each MCO and performance data submitted by the beneficiary support system;
12. Any other data related to the provision of LTSS

The regulation also requires states to conduct readiness reviews at least three months prior to the start of a new program, when a new Plan enters an existing program, and when new populations are being added. CMS did not include changes to geographic areas or new benefits as requiring readiness reviews, as had been proposed. In the preamble, CMS clarifies that the readiness review must commence at least three months prior to the effective date, but need not be

completed prior to the effective date. CMS states in the preamble that states must ensure that the readiness review is completed in sufficient time to resolve or mitigate problems identified through the readiness review to ensure smooth implementation.

The readiness reviews must be submitted to CMS in order for managed care contract changes to be approved. Readiness reviews will consist of a desk review of documents and, for new programs or new Plans, an on-site review that includes interviews with staff and managed care leadership in key operational areas and will address four broad areas:

- operations and administration;
- service delivery;
- financial management; and
- systems management

This is a significant change for New York. Although readiness reviews are currently performed when plans enter new programs or expand service areas, they are not performed when new populations are added. Although DOH does perform network adequacy reviews and requires approval of member educational information, such reviews are not as extensive as that required by the final regulation.

The regulation also requires states to provide an annual program assessment report to CMS no later than 180 days after the end of the managed care plan's period of performance. States that are required to submit a report for a section 1115(a) demonstration project can submit that report for purposes of the new report if the information is duplicative. The report must be shared with the Medical Care Advisory Committee and the LTSS stakeholder group. The first report will be due after the contract year following the release of CMS guidance on the content and form of the report.

The report must provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:

1. Financial performance of each Plan, including MLR experience;
2. Encounter data reporting by each Plan;
3. Enrollment and service area expansion (if applicable) of each Plan;
4. Modifications to, and implementation of covered benefits;
5. Grievance, appeals, and state fair hearings;
6. Availability and accessibility of covered services, including network adequacy standards;
7. Evaluation of Plan performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance;
8. Results of any sanctions or corrective action plans imposed by the state or other formal or informal intervention with a Plan to improve performance;
9. Activities and performance of the beneficiary support system;
10. Any other factors in the delivery of LTSS not otherwise addressed

The requirements relating to monitoring and readiness reviews will apply beginning July 1, 2017.

X. INFORMATION STANDARDS

These provisions will apply beginning with the first rating period on or after July 1, 2017.

In order to address technological advances, the final regulation replaces the existing provisions relating to information standards. The regulation explicitly permits state and Plan beneficiary information to be provided electronically. In the preamble, CMS declines to require individuals to explicitly elect to receive electronic communications. Rather, CMS notes that if an individual provides his or her email address, it is reasonable for states and/or Plans to use it for contacting the enrollee unless the enrollee requests not to receive communications at that email address.

The final regulation requires all states to have a website that either provides directly or by linking to plan websites, managed care member handbooks and provider directories, network adequacy standards, EQR reports, managed care model contracts, encounter data, base data for rate making, MLR standards, base data for solvency reviews, network availability and accessibility documentation, ownership and control and subcontractor information, annual reports of recoveries, and audit reports for audits of encounter and financial data. New York's existing website does not contain all of the information CMS requires nor does New York currently provide links to Plan-specific provider directories or handbooks.

A. Member Materials

In order to improve consistency, states must develop, and Plans must use, model member handbooks and member notices developed by states. In addition, states must develop standardized managed care definitions and terminology, which are based on those in the Uniform Glossary applicable to QHPs.

Information provided electronically must be in a readily accessible format, placed in a location that is prominent and readily accessible, be capable of being retained and printed, and comply with content and language requirements. A paper version of the information must be available within five business days of a request.

States must have a methodology for identifying prevalent non-English languages spoken by enrollees and potential enrollees in each service area. A non-English language is "prevalent" if it is spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient. "Limited English proficient" means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English. States and Plans must make oral interpretation available in all languages. Also, information must be available in written form in each prevalent non-English language. Provider directories, member handbooks, appeal and grievance notices, denial and termination notices, and other notices "critical to obtaining services" must be available in prevalent non-English languages in each Plan's particular service area. These are similar to the requirements applicable to QHPs.

Written materials must also be available in alternative formats and auxiliary aids and services made available upon request. All written materials must also include taglines in each prevalent non-English language and in large print 18 point font explaining the availability of written translations and oral interpretation with the plan's toll-free customer service number. Enrollees and potential enrollees must be made aware that oral interpretation is available for any language and written information is available in prevalent languages, that auxiliary aids and services are available upon request, and how to access those services. All written materials must be in easily understood language and format with a font size no smaller than 12 point.

B. Materials for Potential Enrollees

Potential enrollees must be provided information about rights to disenroll from managed care, including the length of the disenrollment period, basic features of managed care, populations excluded and exempted from managed care, service areas of each managed care plan, covered benefits, benefits provided through fee-for-service, provider directories, formularies, cost sharing, network access and availability requirements, plans requirements to coordinate care, and quality and performance indicators at the time the potential enrollee first becomes eligible to enroll or is required to enroll in managed care. Information must include taglines in prevalent non-English languages and in large print of at least 18 point font that explains the availability or written translations or oral interpretations and provide a toll-free telephone number for counseling services.

C. Member Handbooks

CMS proposes that member handbooks can be provided by mailing a copy, provided by email with consent to receive information in that format, or by posting them to the Plans' websites so long as the enrollee is advised in paper or electronic form of its availability and so long as members with disabilities not able to access the internet are informed that auxiliary aids and services are available upon request.

D. Provider Directories

Provider directories may be made available electronically or in hard copy, if requested, and must include provider names and group affiliations, street address, telephone number, website, specialty information, panel status, cultural and linguistic capabilities and languages spoken, and whether accommodations are available for those with disabilities. The preamble clarifies that for online directories, links to large subcontracted networks, such as pharmacies, are permissible. Paper directories must be updated monthly and electronic directories no later than 30 days from receipt of updated information. Provider directories must be made available in machine readable file and format which would allow for third party aggregation. CMS anticipates issuing clarifying guidance on this provision when additional details on machine readable formats become available.

E. Formularies

Plan formularies may also be made available electronically and must include covered medications by tier including generic and name brand. Like provider directories, formularies must be made available in machine readable file and format which will allow for third party aggregation. Guidance on this requirement will be forthcoming.

The final regulation also applies these Information Requirements to Child Health Plus.

F. Encounter Data and Health Information Systems

States must submit encounter data on a monthly basis and are required to ensure enrollee encounter data is validated for accuracy and completeness and is an accurate representation of the information submitted to the state by plans. Encounter data must include the level of specificity required by CMS, and at least the following: enrollee identifying information, rendering provider, the services or items provided by procedure code, diagnosis, allowed or paid amount, enrollee responsibility, third party liability amounts, and service dates, claim submission dates, adjudication dates and payment dates. Encounter data must be submitted in the HIPAA ASCX12 and NCPDP formats. State must establish benchmarks for accuracy, completeness and timeliness of Plan submitted encounter data.

XI. MISCELLANEOUS PROVISIONS

A. Encounter Data and Health Information Systems

States must submit encounter data on a monthly basis and are required to ensure enrollee encounter data is validated for accuracy and completeness and is an accurate representation of the information submitted to the state by plans.

B. Indian Health Providers and Indian Managed Care Entities

Consistent with existing guidance, CMS finalizes the proposal the require Plans to contract with a sufficient number of Indian health care providers (IHCPs) and allow eligible member to have timely access to covered services, to require that IHCPs, whether participating or not, be paid at a negotiated rate or a rate similar to rates paid to other providers for similar services in a timely manner. Eligible members must be permitted to choose an IHCP as a PCP and to receive services from out of network ICHPs. Out-of-network IHCPs must be permitted to make referrals to in-network providers. In states with too few IHCPs, eligible enrollees must be permitted to access out of state IHCPs.

This provision also applies to Child Health Plus.

C. Provider Discrimination Prohibited

CMS promulgated without change the existing rule prohibiting Plans from discriminating in the participation, reimbursement, or indemnification of any provider acting within the scope of his or

her license or certification solely on the basis of that license or certification. Plans that decline to include individual or groups of providers in its provider network must give affected providers written notice of the decision.

D. Enrollee Rights

CMS promulgated the existing rule requiring that Plans have written policies regarding enrollee rights and requirements to comply with applicable Federal and State laws pertaining to enrollee rights and ensuring employees and providers observe and protect those rights. Enrollees have the right:

- to receive information in an easily understood manner and in their native language,
- to be treated with respect and consideration for dignity and privacy,
- to receive information on available treatment options and alternatives;
- to participate in decisions regarding health care including refusing treatment;
- to be free from restraint or seclusion; and
- to request and receive copies of medical records according to the requirements of HIPAA.

This provision also applies to Child Health Plus.

E. Liability for Payment

CMS continues the current requirement that Plan members cannot be held liable for the Plans debt in the event of insolvency, for covered services if the state does not pay the plan or the plan does not pay the provider for covered services, or any amount in excess of the amount the plan would have paid if the plan reimbursed the services directly.

This provision also applies to Child Health Plus.

F. Cost Sharing

CMS continues the current requirement that Plan members cannot be charged premium and cost sharing that exceeds existing limits placed on enrollee cost sharing in the Medicaid fee-for-service program.

G. Solvency Standards

CMS continues the existing requirement that Plan members cannot be held liable for the Plan's debts if the Plan becomes insolvent and Plans must be licensed as a risk-bearing entity under state laws

H. Confidentiality

CMS continues the existing requirements for Plans to comply with HIPAA standards for use and disclosure of individually identifiable health information.

I. Practice Guidelines

CMS continues the existing requirement that Plans adopt practice guidelines that are based on valid and reliable clinical evidence or a consensus of providers in the field and that they be reviewed and updated periodically as appropriate.

This provision also applies to Child Health Plus.

XII. CHILD HEALTH PLUS PROVISIONS

The regulation revises existing provisions to clarify that CMS may withhold federal financial participation if it finds that the state plan or state practice is in substantial non-compliance with these regulations. Substantial noncompliance includes failure to comply with requirements that significantly affect federal or state oversight or state reporting.

A. CHP Contracts

The regulation includes a number of new contracting standards. States will be required to submit CHP contracts to CMS in accordance with standards specified by the Secretary, and the contracts must include the rate that will be paid to Plans. However, FFP is not conditioned on approval of contracts by CMS, as it is for Medicaid. In addition, contracts must require Plans to accept enrollment in the order in which individuals apply, without restriction and must prohibit Plans from discriminating against enrollees based on health status. Further, contracts must prohibit Plans from discriminating, or using policies or practices that have the effect of discriminating, against enrollees with respect to race, color, national origin, sex, sexual orientation, gender identity, or disability. Contracts must require Plans to submit annual audited financial statements specific to their CHP programs. Consistent with Medicaid, contracts must require Plans to retain records for 10 years.

B. Enrollment

The final regulation does not require states to establish default enrollment processes for CHP, but permits states to do so. New York does not use a default enrollment process.

C. Medicaid Provisions

The regulation applies a large number of Medicaid provisions to Child Health Plus, which will likely require significant changes in operations. Where a Medicaid provision that is revised by the final regulation applies to Child Health Plus, we have indicated this in the discussion of the applicable provision.

The final rule also applies the following existing Medicaid provisions, which were not revised by the rule, to Child Health Plus:

- Emergency and post stabilization services
- Provider-enrollee communications
- Provider selection
- Health information systems