NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

VIA ELECTRONIC SUBMISSION

July 27, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2390-P
P. O. Box 8016
Baltimore, MD 21244-8016

Subject: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability – CMS-2390-P RIN 0938-AS25

The National Association of Chain Drug Stores (NACDS) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding our views on the proposed regulations published on Monday, June 1, 2015 in the Federal Register. The proposed regulations would align the rules governing Medicaid and CHIP managed care with those of other major sources of coverage and implement statutory provisions which would promote the accountability and quality of care provided by Medicaid managed care plans.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies, and employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

NACDS believes that updating the rules related to Medicaid managed care provides an opportunity to protect both patients and providers as the use of managed care in the Medicaid program increases. We are providing these comments in hopes of partnering with CMS in the development of managed care requirements that will not only provide a framework for managed care plans, but will also create standards that will serve to maintain the strong link between Medicaid patients and community pharmacies and the valuable services that these pharmacies provide.

Specifically in our comments, NACDS discusses:

- Covered Outpatient Drugs
- Network Adequacy and Availability of Services

- Program Integrity and Auditing
- Medical Loss Ratio
- Provider Payment Initiatives
- Development of a Medicaid Managed Care Quality Rating System

Covered Outpatient Drugs

More Medicaid beneficiaries are being enrolled in managed care plans. In addition to this transition, states are now including prescription drugs in their managed care plans. In the proposed rule, CMS has established requirements for managed care plans and the coverage of covered outpatient drugs. CMS is requiring managed care plans to provide coverage of covered outpatient drugs in a manner that would meet the standards for coverage of such drugs imposed by section 1927 of the Social Security Act (the Act). In addition, the proposed rules also include provisions for drug utilization reviews (DUR) and prior authorization. Although these provisions are stated in very general terms, this is the first time CMS is promulgating regulations for Medicaid managed care plans related to prescription drug coverage. NACDS applauds CMS for developing rules which would apply these standards to managed care plans. These standards and activities have long been standard for fee-for-service (FFS), and applying these standards to managed care plans demonstrates CMS' recognition of the need for more oversight and responsibility of the managed care entity.

Although we believe that adoption of these proposed regulations will help clarify the responsibilities of plans and stipulate the actions necessary to ensure that plans comply with section 1927 of the Act, we have some additional concerns about ensuring continuity of care and access to prescription drugs as more patients are moved to managed care plans.

> *Unique BIN/PCN/Group Numbers:* Currently, many plans provide prescription drug benefits to patient populations beyond those that are enrolled in Medicaid managed care. This being the case, many plans do not have a method in place to differentiate among Medicaid managed care enrollees, marketplace enrollees, or commercial plan enrollees. Because there is no way to differentiate Medicaid managed care beneficiaries, pharmacies are unable to properly obtain coverage information or otherwise assist the beneficiary as required by the managed care plan. Proper identification of Medicaid managed care beneficiaries is essential and necessary for payment, auditing, quality measurement, and monitoring purposes.
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> Assigning unique BIN/PCN/Group numbers for Medicaid managed care plans will allow pharmacies to clearly identify and handle Medicaid managed care claims. This will also enable pharmacies dispensing 340B drugs to distinguish these claims from the managed care commercial claims for covered drugs. In addition, the use of unique BIN/PCN/Group numbers will give pharmacies the capability to properly coordinate benefits in cases where beneficiaries may have other third party coverage. Therefore, we urge CMS to encourage states to

require managed care plans to create and assign unique routing, beneficiary identifiers, and group numbers exclusive to Medicaid managed care beneficiaries.

No Mandatory Mail Order: While the proposed rules would create a framework for plans to follow with regard to covered outpatient drugs, NACDS believes that CMS should require states to develop requirements that would ensure patient choice to all healthcare providers. In most cases, states create strong financial incentives for patients to use mail order instead of their local community pharmacy and often mandate that their enrollees obtain maintenance medications and other specialty or high cost drugs through a mail order program. We urge CMS to require states to develop provisions that would not only ensure patient choice, but would also prohibit managed care plans from imposing financial incentives that would steer patients to use mail order pharmacy services.

Patient choice should not be restricted once patients are enrolled in a managed care program. It is apparent from the continuous growth in state Medicaid expenditures that Medicaid patients tend to be sicker and require more heath care, especially prescription drugs. Medicaid patients would continue to benefit from coordinated prescription management by their local pharmacist, which would be in jeopardy if states and plans are allowed to continue to pursue mandatory mail order services.

Section 1902(a)(23) of the Act allows beneficiaries to obtain services from any qualified Medicaid provider that agrees to provide such services. While there are waiver options for managed care plans in that regard, we believe patients that are transitioned from fee-for-service to managed care plans should be allowed the same protections of using the provider of their choice. NACDS and its members also believe that allowing patients the freedom of choice to use the community pharmacies they have come to know and trust is a positive step towards improving patient adherence to their medication regimens. Poor medication adherence costs the nation approximately $290 billion annually – 13% of total healthcare expenditures – and results in avoidable and costly health complications, worsening of disease progression, increased emergency room visits and hospital stays. This inadequate medication adherence rate is associated with about $47 billion annually for drug-related hospitalizations, and estimated 40 percent of nursing home admissions.[1] Development of rules that prohibit mandatory mail order will serve as an important tool to help ensure that patients take their medications as prescribed as well as improve health outcomes and reduce overall healthcare cost by decreasing the use of more costly medical interventions such as emergency room visits and hospitalizations.

Properly Defined Specialty Drugs: In addition to the financial incentives for patients' use of mail order services, some states and managed care plans create aggressive specialty drug programs that often mandate that their enrollees obtain specialty or high cost drugs through a mail order program. As we mentioned

[1] NEHI, 2011.

above, we believe that patient choice should not be restricted once patients are enrolled in a managed care program. We believe that CMS should urge states to develop requirements that would prohibit managed care plans from limiting specialty medications through closed, exclusive networks. Patients should have access to their specialty medications through retail pharmacies with specific specialty clinical management capabilities that meet patients' needs. Such access can be critical to maintaining the health of vulnerable patients with chronic illnesses.

Understanding how specialty drugs are dispensed is an important component of determining the regulatory framework for specialty drugs. In this regard, NACDS conducted an analysis of the utilization of the drugs most commonly classified as specialty drugs by third party payers, which shows that the majority of these drugs are dispensed in retail settings. Recognizing the integral role of community retail pharmacies for dispensing specialty drugs, the chain pharmacy industry is committed to supporting an approach to the regulation of specialty drug benefits that provides patients with prescription drug services that optimize the patient's healthcare outcomes and provides patients with the convenient readily accessible community pharmacies for specialty prescription drugs as well as their other prescription drugs. The well-being of our patients is the top priority for chain pharmacies.

We believe that states and managed care plans should properly define specialty drugs and states should develop standards on how managed care plans determine which drugs are included on specialty drugs lists. The definition of specialty drugs should be created in a way to avoid inappropriate categorization of drugs. To do this, we suggest the following key policy principles that will help ensure that specialty drugs are properly defined, categorized, and limited to those certain complex medications that are used to treating very complex disease states. In addition, the definition will serve to ensure that Medicaid patients receive the well-recognized benefits that community pharmacies provide that benefit patient healthcare outcomes for their specialty drugs:

- Specialty drugs should not be subject to requirements or limitations that would force specialty drugs into mail order or restricted networks, or that would limit patients from obtaining specialty drugs from community retail pharmacies to certain circumstances such as emergency or immediate use. Patients should have the choice to determine where they obtain their specialty drugs.
- The definition should not be based solely on cost and should focus on the clinical aspect of the drugs in question, such as clinical oversight, storage, handling, patient education, and monitoring.
- The definition should require that all drugs under consideration meet all of the listed criteria before being added to a specialty drug lists.

- The definition should adequately define retail community pharmacy as defined by Affordable Care Act (ACA, which clearly excludes mail order pharmacy.
- The definition should allow patients to have a choice to receive specialty drugs through the retail setting, and if specialty drugs are provided through mail order, it should be solely for limited exceptions, to ensure that there is a valid reason for such a limitation.
- The definition should ensure that all pharmacy stakeholders have sufficient advance notice of and an opportunity to review and comment on the mail order only drugs lists, and to receive a written explanation of the reasons for the limitation of where such drugs may be dispensed.

To support these principles, chain pharmacy has prepared and offers the attached definition of specialty drugs. (Attachment One)

Transparent, Fair and Honest Pricing: Often, contracts between managed care plans and pharmacies do not include the most basic information, such as the methodology for how pharmacies are reimbursed. Even after pharmacies sign contracts, manage care plans reduce reimbursement without notification. This places retail pharmacies, which operate on an average profit margin of about two percent, in the position of dispensing drugs at a financial loss.

As a part of the framework that CMS creates for managed care plans to follow, we ask CMS to urge states to implement requirements that would help level the playing field between managed care plans and neighborhood pharmacies. For example, managed care plans could be required to include in all contracts clear pricing terms and objectives that are consistent with both marketing and pricing practices. By law, states are required to ensure that Medicaid reimbursement rates are set at a level adequate to enlist a sufficient number of providers to ensure that care and services are available under Medicaid at the same level as they are available to the general population.[2] Developing provisions that would require managed care plans to include in all pharmacy provider contracts clearly defined drug pricing methodologies, routinely updating drug pricing, paying pharmacies promptly, and allowing pharmacies to contest changes in their reimbursement can accomplish this. We believe such rules and requirements would encourage pharmacy participation, resulting in increased access and options for Medicaid beneficiaries, ultimately leading to improved health and reduced overall program costs.

Maximum Allowable Cost (MAC) Pricing: To address concerns with transparency in pricing, NACDS suggests CMS urge states to develop rules that would require managed care plans to adequately define when a MAC can be established, how such lists should be updated and provided to pharmacies in a timely manner, and how a pharmacy may challenge a particular rate decision.

[2] 1902(a)(30)(A) Social Security Act; 42 U.S.C Section 1936a(a)(30)(A)

We propose that CMS call upon to states to require that a MAC shall be:

(1) Established for any drug with at least three (3) or more therapeutically equivalent, multiple source drugs as determined by the FDA or when only two products are available during a generic exclusivity period, as defined by Federal statute 21 USC §355, with a significant cost difference; and

(2) Determined using comparable drug prices obtained from multiple nationally recognized comprehensive data sources including: wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are nationally available and available for purchase locally by multiple pharmacies in the state. A MAC shall be established for a product using only equivalent drugs as determined by the FDA.

   i. For those drugs in which MAC pricing applies, the managed care plan shall include in contracts with pharmacies information regarding which of the national compendia is used to obtain pricing data used in the calculation of MAC pricing and shall:

      a. Make MAC price adjustments at least twice a month and shall provide pharmacies with prompt notification of any changes or additions made to the MAC list and MAC rates at that time, except when a price for a drug changes by more than 100%, in such cases the MAC price adjustment for that drug shall be made within three business days of the change in price; and

      b. Provide a process, to allow providers to submit 200 claims per MAC appeal, in an Excel file, containing all National Drug Codes (NDCs) within the Generic Product Identifier (GPI), along with allowing pharmacy providers to comment on, contest, or appeal the MAC rates and MAC list. The right to contest should be limited in duration and shall provide for retroactive payment in the event it is determined that MAC pricing has been applied incorrectly.

         i. If the challenge is successful, the managed care plan shall make an adjustment in the drug price to the date of the originally challenged claim, and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the managed care organization or pharmacy benefit manager, as appropriate.

         ii. A network pharmacy retains the right to collect or not collect additional appropriate co-payments from a patient after adjustments in the drug price after a successful challenge.

   ii. The managed care plan shall make all applicable MAC lists, including all changes in the price of drugs, available to network pharmacies upon request in a readily accessible and usable format, such as Excel, CSV,

TXT or Comma Delimited file, which contains a complete list of the drug name, NDC, package size, per unit price, strength of drug, GPI, and Generic Code Number (GCN). In the event there are multiple MAC lists under the same contract, the contract shall identify which MAC lists are appropriately applicable.

Predictive Capabilities: Pharmacies are reimbursed for generic drugs based on MAC lists. The MAC list establishes the amount the pharmacy will be reimbursed for a particular generic medication. As previously stated, pharmacies are unaware of the methodology used in the development of the MAC list or the determinations and calculations that go into updating the MAC list. It is even unclear as to the frequency at which MAC lists will be updated. This lack of transparency, combined with recent dramatic acquisition cost swings in the generic drug market, makes it difficult for pharmacies to predict how much they may be reimbursed for a particular drug, not only week to week, but over the term of the contract. The ability to address volatility in drug cost pricing is essential to pharmacies' abilities to engage in business planning. A transparent and predictable reimbursement methodology will produce a more effective and efficient program overall, which will lead to increased health outcomes and decreased program costs. NACDS suggests that CMS urge states to incorporate the following language to address these concerns:

1. A managed care plan shall include in contracts with pharmacies a process for no less frequent than once a week updates to pharmacy product pricing files used to calculate prescription prices that will be used to reimburse pharmacies.

2. A managed care plan shall provide a contractual commitment to deliver a particular average reimbursement rate for generics (for example, a maximum discount on multi-source generics as a whole, often referred to as a "generic effective rate"). The average reimbursement rate for generics (e.g., "generic effective rate") shall be calculated using the actual amount paid to the pharmacy, such as through patient co-pays and plan reimbursement, excluding the dispensing fee and claims paid at the pharmacy's usual and customary price and shall not be calculated solely according to the amount allowed by the plan. The plan shall disclose to the network pharmacy the methodology used in determining the generic effective rate.

3. A managed care plan may not charge a transaction fee for claims submissions provided in an electronic format by a healthcare provider.

Requiring fair and transparent contractual terms related to pharmacy pricing will benefit pharmacy providers, as well as ensure the Medicaid program is given a clear understanding of what it is paying for in terms of prescription drug costs. CMS has recently taken steps to increase the transparency of Part D drug pricing. We believe the Medicaid program would benefit from increased transparency as well.

The setting of a Medicaid Rate Floor for Pharmacy: In some states where there are large managed care populations, the state has created a reimbursement floor for participating providers which would guarantee that providers were not paid below the current Medicaid fee-for service rates. However, these same payment reassurances and protections have not been extended to pharmacy providers when prescription drugs are carved into the managed care programs. In addition, although some states have established a minimum dispensing fee, the state failed to take into consideration the other component, of pharmacy reimbursement methodology, ingredient cost, which could result in huge reimbursement issues and unwarranted confusion among plans.

As CMS works to create a framework for managed care plans, we ask you to require states to ensure that payment rates are at levels that help to preserve patient access once transitioned to managed care. In order to maintain equitability among providers within manage care plans, CMS should require states to apply the same level of reassurance and reimbursement protections for all participating providers, including pharmacy providers. Establishing the same reimbursement rate floor for pharmacies will increase transparency as well as create a level playing field for all providers, thereby allowing for some fiscal stability and predictability of reimbursement in these private contracts.

In addition, CMS should strongly urge states and managed care plans to take into consideration the fact that the fee-for-service reimbursement rates in eight states are based on either a state or national pharmacy survey of the actual invoice cost of prescription drugs.[3] In these eight states, cost is determined by the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. Thus, if states and managed care plans were to use the fee-for-service rate as a reimbursement ceiling, as opposed to a floor, it would result in pharmacy providers being reimbursed below the actual cost of acquiring the drug products. Accordingly, pharmacies would face increasing financial burdens, which could potentially lead to access issues for Medicaid beneficiaries. Therefore, NACDS and its members believe that in order to establish a rate floor that is accurate and relevant, CMS should require states to consider adequate dispensing fees and incorporate a built-in inflationary component per annum of Consumer Price Index for its dispensing fee. By incorporating a built-in inflationary component to the dispensing fee, pharmacy providers will receive reimbursement that is much more reflective of the cost to provide healthcare services in the marketplace.

Cost to Dispense OTC Drugs: Under the proposed rule, CMS would require managed care plans to provide coverage of covered outpatient drugs in a manner that would meet the standards for coverage of such drugs imposed by section 1927 of the Act. Likewise, under section 1927(d)(2) of the Act, states and now

[3] Alabama, Colorado, Idaho, Iowa, Louisiana, Oregon- State calculated actual acquisition cost for pharmacy ingredient cost reimbursement. Alaska and Delaware: National Average Drug Acquisition Cost calculated and posted by CMS.

managed care plans will have the flexibility to either exclude from coverage or otherwise restrict coverage of over-the-counter (OTC) drugs. While this coverage may vary from plan-to-plan and state-to-state, we believe that, at a minimum, state and managed care plans should be required to establish fair and adequate dispensing fees for OTC products in the same manner as prescription drugs. Although there may be substantial differences in the cost of an OTC drug compared to a prescription drug, the overall cost to dispense an OTC drug is the same as a prescription drug. In current practice, pharmacists are required to follow the same process, level of effort, and utilize similar resources for all prescriptions, regardless of whether a drug is an OTC drug or not. Accordingly, the dispensing fees for OTC drugs should adequately reflect the true cost of dispensing these products. Therefore, we urge CMS to require states to implement adequate and fair dispensing fees for all managed care claims, including OTC drugs.

Prompt Pay: In addition to ensuring fair and honest payment to pharmacies, we believe that CMS should urge states to require managed care plans to pay all pharmacy claims in a timely manner. All Medicaid pharmacy claims should be paid within 14 days for clean claims submitted electronically, and 30 days for all other clean claims, which is the current requirement in Medicare Part D. Furthermore, similar to the prompt pay standards used under Medicare Part D, managed care plans should be required to submit payment via Electronic Funds Transfer (EFT), if so requested by provider, and at no charge to the provider. Lastly, managed care plans should also be required to pay interest for late payments, and have procedures in place to correct defective/unclean claims.

Standardization of Medicaid Managed Care Formularies and Coverage: Due to the large shift to Medicaid managed care, Medicaid beneficiaries face multiple barriers to understanding their new plan formularies, to determining which of their medications are covered, and to exploring if there are other plans that they should consider enrolling in to meet their needs. Plan formularies vary greatly and this process can be extremely complicated for patients. Community pharmacists are dedicated to assisting patients with this difficult process and are committed to communicating with healthcare providers if changes in therapies should be considered due to plan coverage. We believe that CMS should urge states to develop requirements that would require all contracted managed care plans to function under a standard formulary. Managed care plans should not have the authority to determine which medications patients should be taking. It should be up to the healthcare provider to determine the best course of treatment, but given formulary limitations and restrictions, this is often not the case. We believe that CMS should require states to take a more active role in trying to eliminate the great variation in plan formularies to ensure widespread patient access to needed prescription medications which helps to prevent the need for more costly care.

Network Adequacy and Availability of Services

NACDS supports network adequacy standards that promote access based on enrollees' needs, availability of care and providers, and utilization of services. We believe that the final rule should include a framework that will serve as a tool to ensure that plans maintain beneficiary access to their current providers. Patients should be allowed the freedom to select a pharmacy that best fits their personal health needs and provides the most accessible care. Restrictive provider networks are not appropriate for Medicaid recipients. Medicaid beneficiaries are less mobile than the general population as they rely more heavily on public transportation and have fewer options for traveling to providers that are not conveniently located. Restricting provider networks results in restricted patient ability to access their healthcare providers and unnecessary disruptions in needed care. As a result, there is the potential for increased overall healthcare expenditures due to the use of more costly healthcare services among Medicaid patients. Therefore, in order to ensure continuity of care and minimize healthcare costs, Medicaid managed care plans should be required to maintain open networks that would allow patients continued access to providers they have come to know and trust.

Under the proposed rule, managed care plans will be required to establish time and distance standards for pharmacies. However, the rule does not provide specific parameters or guidelines for states or managed care plans to follow, but rather solicits stakeholder comments on whether specific measures, (i.e. time and distance, provider-to-enrollee ratios per provider type, per county or other geographic basis) should be used.

In order to ensure that patients have access to the pharmacy of their choice, at a minimum, CMS should require Medicaid managed care plans to follow the same pharmacy access standards as required for the Medicaid fee-for-service program by allowing any pharmacies willing to accept a plan's standard terms and conditions the opportunity to participate in a managed care plan network. By adopting the same fee-for-service standards, Medicaid patients would have access to a sufficient number of locations from which to get their medications. These standards would also decrease the likelihood that patients will face access barriers and may not be able to get their prescriptions when they need them, thus helping to prevent non-adherence and associated health complications and costs.

Furthermore, NACDS believes that if the intent of the proposed rule is to align the regulations governing Medicaid and CHIP managed care with those of other major sources of coverage, such as Medicare Advantage (MA) and Medicare Part D (Part D), then the same access standards that apply to the MA and Part D plans should also be used for Medicaid managed care. In the case of retail pharmacy, the Medicare Part D program has clear requirements for its beneficiaries' access to prescription drugs and pharmacy services. Specifically, the standards require that 90 percent of beneficiaries in urban areas have access to a pharmacy within 2 miles, 90 percent of beneficiaries in suburban areas have access to a pharmacy within 5 miles, and 70 percent of beneficiaries in rural areas have access to a pharmacy within 15 miles. We believe these standards work well in ensuring beneficiary access, and encourage their adoption in the Medicaid Managed Care Final Rule.

In addition to defining the access standards, we urge CMS to finalize the Methods for Assuring Access to Covered Medicaid Services Proposed Regulations published on May 6, 2011, which would allow for more oversight in the process to ensure adequate patient access once standards have been adopted.[4] In the Methods for Assuring Access to Covered Medicaid Services Proposed Rule, the agency stated its commitment to developing proposals for monitoring access in the managed care setting. As such, the rule discussed the importance of "sufficient" access, and how states' payment rate changes do not comply with the Medicaid access requirements if they result in a denial of sufficient access to covered care and services. In order to strengthen the standards and agency oversight regarding patient access and state rate setting methodologies—for services in both Medicaid managed care and fee-for-service—it is important that CMS finalize rules to enforce the patient access laws. We believe that until these requirements are fully implemented through the final rulemaking process, there is insufficient authority or oversight in the process that would ensure adequate patient access once standards are established and implemented by managed care plans. Furthermore, we believe that when finalized, the Medicaid Rate Setting Proposed Rule should create a guidance process for states and managed care plans to determine if they are meeting the federal Medicaid access standards.

Program Integrity and Auditing

The proposed rule expands inspection and audit rights so that the state, CMS, and the Office of the Inspector General (OIG) may conduct inspections and audits at any time of facilities where Medicaid related activities and work is conducted. We support CMS' efforts to control fraud, waste, and abuse within the Medicaid program. However, we have concerns with aggressive auditing practices and believe that the final rule should provide a balance between the need to ensure integrity in the Medicaid program and the need to afford due process and equal protection to providers.

Pharmacy providers have always been subject to intense auditing by states. Accordingly, we believe that these provisions should include additional safeguards for pharmacy providers. While we applaud CMS' efforts to promote integrity in the Medicaid program and identify and punish Medicaid fraud and abuse, NACDS and its member companies strongly support efforts to provide due process protections for Medicaid providers who are subject to audits. We ask CMS to include provisions that would require procedures to provide such due process protections. Below are some suggestions that we ask CMS to consider when establishing fair procedures, practices, and standards in Medicaid audits.

> *Oversight of Auditing Activities:* As with any auditing process, there are likely to be issues and provider concerns that need to be addressed. To ensure that there is proper oversight of auditing activities, CMS should include provisions that require a Medicaid auditing project officer. The primary function of the project officer would be to closely monitor auditors to identify issues within the auditing process and resolve those issues in a timely manner. In addition, the project manager should serve as a point of contact to providers and be readily accessible

[4] CMS-2328-P; RIN 0938-AQ54, Medicaid Program; Methods for Assuring Access to Covered Medicaid Services; May 6, 2011 in the Federal Register.

to work with providers to address any concerns that the provider cannot resolve directly with the auditor.

Look Back Period: CMS should provide guidance on the auditing look back period, which should not exceed more than eighteen months from the date that the claim being audited was adjudicated. Allowing the review of claims that are older than eighteen months increases the administrative burden on pharmacies to research claims that may or may not be kept in house. Thus, an undetermined or lengthy look back period subjects providers to research claims that are possibly too old for the provider to work with the state or plan to obtain proper payment if those particular claims were in fact adjudicated incorrectly.

Third Party Liability: Beneficiaries may have more than one form of coverage for prescription drugs and can switch between Medicaid managed care plans. In cases where retroactive other coverage is identified or cases where beneficiaries switch managed care plans, most plans require the pharmacy provider to identify the other coverage and resubmit claims to the primary insurance carrier. This is a disjointed, inefficient, and costly process in which most cases a retrospective third party liability is identified and pharmacies are required to reverse and rebill claims that have been paid in error. This not only adds to the administrative burden of reversing such claims, but it also improperly shifts the financial risk from the plan to participating pharmacies if payment is not received for those prescriptions that have already been dispensed and used by the beneficiary.

Because coverage differs from plan-to-plan there is an increased possibility that the prescriber and/or drug may not be covered, prescribed quantity and/or days' supply may not be covered, patients may have a higher copayment or be subject to new deductible requirements, or the claim may be too old to receive payment through an electronic process, thus requiring paper claims or other processes to receive payment. Furthermore, if a claim was originally adjudicated and accepted online and it is determined that retroactive disenrollment has occurred, pharmacies will not have an opportunity to file with any other insurance because commercial insurance, generally will not accept dated claims. We believe that as managed care plans attempt to recoup payments, plans should be limited to no more than eighteen months look back period to ensure that pharmacies are resubmitting claims within the new plans billing window and can receive payment for the drugs that have been dispensed.

NACDS and its members understand the need to have the correct payer cover the impacted claims, and agree that this process has to be done in line with the current federal requirements. As stated in the proposed rule and under section 45 CFR 162.1901, the Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the state has paid on behalf of a Medicaid recipient. This provision allows Medicaid agencies to use the subrogation standard to pursue reimbursement from other

payers, not providers. We believe this provision is also applicable to managed care plans providing coverage to Medicaid beneficiaries seeking reimbursement from other plans. In addition, we believe that this provision provides managed care plans the appropriate mechanism to seek payment of these claims directly from the new plan provider without inadvertently causing undue and onerous administrative and financial burdens on pharmacies who have acted appropriately in the prescription filling and adjudication processes.

Record Requests: Failure to limit the number of record requests from providers can cause significant administrative burdens and inhibit a provider's ability to respond to audit requests in a timely manner. Providers are subject to numerous audits. To allow pharmacies to respond timely to record requests, audits should be limited to the number of records that can be requested from a provider. In addition, auditors should be required to accept medical records electronically and to reimburse providers for reasonable shipping and copying costs or other administrative costs associated with providing non-electronic records.

Suspension of Payment and Recoveries of Overpayment: Under the proposed rule, CMS will require that states develop provisions for managed care plans to suspend payment to network providers when the state has determined there is a credible allegation of fraud. Managed care plans should not be permitted to recoup or offset disputed overpayments until after final findings, further review has been done of the auditing process, or in case of an appeal, after the appellate process is final. As previously stated, pharmacies operate at a very small net profit margin of approximately 2 to 3 percent, a profit margin that has been continuously shrinking due to increasing product, labor, and administrative costs. Suspending or recouping payment to pharmacy providers without allowing pharmacies the right to appeal any findings will pose a real threat to pharmacies' continued financial viability and, in turn, to the ability of low-income patients to access prescription drugs and pharmacy services. Allowing pharmacies the right to an appeal before suspension of payment or recouping alleged overpayments lessens this financial burden to pharmacies as well as allows pharmacies the ability to dispute any findings that may have resulted from administrative error.

As written, the proposed rules are unclear as to what is considered a credible allegation, therefore, we strongly urge CMS to further define credible allegations. Without a proper definition of what constitutes a credible allegation there is increased risk that provider payments will be suspended unjustly. We also urge CMS to consider the further establishment of regulatory standards regarding the conducting of audits and the suspension and/or recovery of overpayments. In the absence of such standards and guidelines, state auditors have limitless authority to conduct audits in any way that they deem appropriate. Due process protections will give Medicaid providers assured fairness and integrity in the auditing process; moreover, patients will be protected by ensuring continued access to their healthcare providers.

Prohibition of Extrapolation: States and managed care plans should be prohibited from using any audit program that bases its finding on extrapolation. Extrapolation audits have been shown to be unreliable and inequitable. They result in unfair, erroneous, and overbroad reaches to the recoupment of funds that, in most instances, should not be subject to recoupment. When used in an audit, estimated overpayment amounts are based on the unproven assumption that the problems found in the sample occur at a similar frequency for all prescriptions filled by that provider during a specified period. Accordingly, recoupment amounts are also assessed on the unproven assumption that the estimated overpayments hold true for all prescriptions filled during the review period. As a result, pharmacies are being asked to repay amounts that are much larger than the payments questioned in the sample.

NACDS believes that all audits should be based on reasonable and fair examination of claims. Therefore, we strongly urge CMS to require states to develop standards and guidelines for managed care audits that will ensure that all Medicaid audits are conducted using generally accepted auditing standards and in accordance with state and federal law.

Medical Loss Ratio (MLR)

Under the proposed rule, CMS will require all plans to calculate and report a MLR each year, starting in January of 2017. CMS believes that a common national standard for calculating MLR will allow comparability across states, facilitate more accurate rate setting, and reduce the administrative burden on managed care plans that operate in multiple states or have multiple product lines. The proposed standards for calculating the MLR are consistent with the standards applied by Medicare Advantage plans and the private plans. However, the rule allows some variation to account for the unique characteristics of the Medicaid and CHIP programs. NACDS believes that Medication Therapy Management (MTM) should be included in the MLR calculation as a healthcare improving activity and not an administrative activity.

According to the Medicare Program Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, MTM will be considered as a part of the MLR calculation if the services meet the definition of activities that improve healthcare quality by improving health outcomes, preventing hospital readmission, reducing errors, and promoting health and wellness.[5] We believe that the same criteria should apply to the inclusion of MTM in the MLR calculations for managed care plans. MTM services are designed to improve health quality, increase the likelihood of better health outcomes, are directed towards individual beneficiaries, and are recognized by professional medical associations, nationally recognized healthcare quality organizations, and governmental agencies, most importantly by CMS itself.

[5] Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule; CMS-4173-F; RIN 0938–AR69; Federal Register; Vol. 78, No. 100 ; Thursday, May 23, 2013

Currently, MTM activities are considered administrative costs. Improvements to the program via additional beneficiary services would increase plan bids and premiums, potentially impacting a plan's ability to compete in the market. In general, MLR protects patients against plans spending too much on administrative overhead or profits instead of paying for health services or quality improvement initiatives. One way to achieving this would be to reclassify MTM activities as "quality improving" under the MLR. Overall, institution of MLR with the inclusion of MTM should help ensure plans are spending adequate dollars on patient care and should not negatively affect beneficiary access to care or the quality of care patients receive.

Provider Payment Initiatives

In the proposed rule, CMS allows states the authority to require managed care plans to adopt value-based purchasing (VBP) models for provider reimbursement or other alternative payment models intended to recognize the value or outcomes of services. The proposed rule also gives states the authority to require managed care plans to participate in multi-payer delivery system reform or performance improvement initiatives as well as adopt minimum fee schedules for all providers that provide particular services under the contract. We believe that improved care coordination and chronic care management are the cornerstones of the VBP models, and medication management is central to both of these objectives. Any effort to improve quality and reduce costs in the long-term will be difficult to achieve if patients do not take their medications appropriately and/or their adherence is poor. Considering the growing evidence that pharmacists are uniquely positioned to improve medication management across the care continuum, and provide a range of health services in the community and as part of care teams, community pharmacies should play a greater role in the VBP movement.

Community pharmacies are the face of neighborhood healthcare. The innovative programs of chain pharmacies deliver unsurpassed value - improving health and wellness and reducing healthcare costs. Through innovative community pharmacy services such as medication therapy management, immunization administration, health education, screenings, simple laboratory examinations and procedures, and disease management programs, community pharmacies play an instrumental role in improving overall outcomes, enhancing patients' quality of life, and the prevention of more costly healthcare treatments. Managed care organizations should be required to incorporate the innovative services provided by community pharmacies in the delivery of health services to Medicaid patients.

While VBP models have primarily focused on physicians and hospitals, they are now expanding to include more providers. The VBP goal is to align performance and health outcomes with compensation by assessing performance using quality and health metrics, and to provide tools and programs to improve patient health outcomes. VBP reform has the potential to improve outcomes, enhance care coordination, and create more system efficiencies. The contribution of community pharmacy in helping achieve the goal of VBP models is extremely promising.

NACDS and its members believe that successful outcomes for a VBP model and other coordinated care programs will be dependent on making sure multiple provider types are able to provide their services to beneficiaries. This should include the multitude of services provided by community pharmacies. Pharmacists play a key role in helping patients take their medications as prescribed and offer a variety of pharmacist-delivered services, such as MTM, to improve quality and outcomes. NACDS urges CMS to require states to ensure pharmacists are able to provide the greatest value to Medicaid beneficiaries by requiring managed care organizations to reimburse pharmacies accordingly for the innovative services provided by community pharmacists to the extent pharmacists are allowed to provide those services under state law. Immediate access to these types of services will not only increase the overall health of Medicaid patients but will also result in a decrease in overall healthcare costs.

Development of a Medicaid Managed Care Quality Rating System

NACDS and its members are strongly committed to ensuring that patients have to access to high quality healthcare services. We recognize the importance of developing and implementing a meaningful Quality Rating System (QRS) for Medicaid Managed Care plans with the overarching goal of providing transparent, actionable ratings to the public based on healthcare quality and outcomes, consumer experience, and cost.

NACDS looks forward to working closely with the agency as it builds this program over the next three to five years. As CMS develops the initial concept for the program, we offer the following recommendations:

> *Ensure the Incorporation of Proven Medication-Related Metrics:* Medications are the primary intervention to treat chronic diseases, and medications are involved in 80% of all treatment regimens. As previously stated, despite the positive results achieved by patients taking their medications properly, poor medication use in all its manifestations has been reported to cost $290 billion annually – 13% of total healthcare expenditures.
>
> Substantial evidence links improved adherence to reduced hospitalizations, delayed progression of disease, improved treatment outcomes for chronic disease, and cost savings.[6] Recognizing this, CBO has revised its methodology for scoring proposals and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall medical spending. In other words, when patients adhere to their prescription regimens and properly fill their medications, they avoid more costly future medical interventions, thereby decreasing overall Medicaid spending. When projected to the entire population this translates to a savings of $1.93 billion in overall healthcare costs, or a savings of $6.19 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

[6] Agency for Healthcare Research and Quality. Medication Adherence: Comparative Effectiveness. Evidence Report / Technology Assessment. Number 208; New England Healthcare Institute. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. August 2009.

Medication-related measures are particularly important to Medicaid beneficiaries, given the challenges they face financially. Consequently, we urge CMS to ensure the incorporation of strong medication-related measures as part of the Quality Rating System for Managed Medicaid plans. Such measures would help to ensure the best quality care for Medicaid beneficiaries while also helping to ensure that managed care programs are operating more efficiently.

Ensure Alignment of Medication-Related Measures Across CMS Quality Programs: NACDS concurs with the recommendation that the QRS for Managed Medicaid plans should be primarily modeled after the Quality Rating System for the Health Insurance Marketplace, given the similarities in patient populations, and the expected transition of patients between Medicaid and Marketplace plans. NACDS also concurs with the recommendation that the Medicare Star Ratings program also be used as a model, given the overlap in dual eligible populations.

Medication-related measures have been a core component of each of these programs. For example, in 2012, CMS launched five (5) medication-related adherence measures as part of the Medicare 5-Star Part D program. The importance of these measures within the Medicare Part D Program is reflected in the overall weight of the measures relative to others. Specifically, the medication-related measures account for nearly half of the overall weighting for the star ratings for PDP plans and twenty percent (20%) for the weighting for Medicare Advantage plans.[7] The specific medication-related quality measures of the Medicare 5-star ratings program are:

1. Medication Adherence for Diabetes Medications
2. Medication Adherence for Cholesterol Medications
3. Medication Adherence for Hypertension Medications
4. High Risk Medication Use in Elderly Patients
5. Appropriate Treatment of Hypertension in Persons with Diabetes

CMS has continued to augment the medication-related measures in the Medicare Star Ratings Program. Specifically, CMS has added the Completion Rate for Comprehensive Medication Review measure, and has indicated it will add the Statin Use in Persons with Diabetes measure in 2018.

Similarly, the final 2015 Quality Rating System Beta Test measure set for the Marketplaces includes three medication-related quality measures:

1. Medication Adherence for Diabetes Medications
2. Medication Adherence for Cholesterol Medications
3. Medication Adherence for Hypertension Medications

[7] Nau, D. The Quality Revolution: Leveraging Star Ratings in Medicare and Other Opportunities for Pharmacy. August 26, 2012.

Thus, both the Medicare Star Ratings Program and Quality Rating System for the Marketplaces include medication adherence measures. Similar incorporation of these measures in the envisioned Quality Ratings System for Managed Medicaid Plans would promote alignment of quality goals across CMS programs, and should thus be a top priority for the Medicaid program.

Balancing State Flexibility with Provider Burden: CMS proposes that each state apply a methodology and weighting to their quality rating system. NACDS has concerns about the burden that may be placed on providers, including pharmacies, given that health plans structure downstream incentives and disincentives to providers related to quality measures in public programs. If there are substantial differences among states in weighting or methodology for medication-related measures, it may 1) increase the reporting burden on providers; 2) send unclear messages about quality priorities; and 3) make it difficult for providers – especially those that operate across state lines – to set and achieve quality improvement goals. As such, NACDS encourages CMS to provide strong national guidance on measure methodology and weighting, and allow states to seek waivers from these if they can demonstrate a substantial state-specific purpose to adjust methodology.

Conclusion

We thank you for the opportunity to comment on the proposed rule. NACDS and its members support efforts to develop a framework and rules to govern managed care plans that will ensure patient access to all healthcare service and we look forward to working with CMS on these very important issues.

Sincerely,

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Vice President, Public Policy and Regulatory Affairs

Attachment One

Specialty Drugs: Model Definition

(A) DEFINTION OF SPECIALTY DRUG - A prescription drug shall be designated as a specialty drug only if it meets all of the following criteria:

(i) The drug cannot be routinely dispensed at a majority of retail community pharmacies as defined in Section (C) due to physical or administrative requirements that limit preparation and/or delivery in the retail community pharmacy environment. Such drugs may include but are not limited to chemotherapy, radiation drugs, intravenous therapy drugs, biologic prescription drugs approved for use by the Food and Drug Administration in accordance with 42 U.S.C.A. § 262, and/or other drugs that require physical facilities not typically found in a retail community pharmacy environment, such as a ventilation hood for preparation;

(ii) The drug is used to treat complex, chronic, or rare medical conditions

a. that can be progressive,
b. that can be debilitating or fatal if left untreated or undertreated; or
c. for which there is no known cure;

(iii) The drug requires special handling, storage, and/or has distribution and/or inventory limitations;

(iv) The drug has a complex dosing regimen or requires specialized administration;

(v) Any drug that is considered to have limited distribution by the FDA

(vi) The drug requires (1) complex and extended patient education or counseling, (2) intensive monitoring, or (3) clinical oversight; and

(vii) The drug has significant side effects and/or risk profile

(B) UPDATING THE SPECIALTY DRUG LIST - The Department shall update the specialty drug list every 90 days, and shall provide a process to allow adequate time for public review and comment, including the right to contest or appeal the inclusion of certain drugs on the list prior to its implementation. All subsequent lists shall take into consideration any comments and suggestions submitted for previously published lists.

(C) DEFINITIONS- For purposes of this section-

(i) Retail community pharmacy.—the term "retail community pharmacy" is defined in accordance with Section 1927(k) (10) of the Social Security Act and means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, home infusion pharmacies, home healthcare providers, or pharmacy benefit managers.