MISSISSIPPI DIVISION OF MEDICAID

Public Comments

State Plan Amendment (SPA) 17-0002

Pharmacy Reimbursement

January 20, 2017

Meg Pearson, PharmD, MS, Director
Mississippi State Department of Health Pharmacy
3156 Lawson Street
Jackson, MS 39213

I appreciate your clarification on some items within the Medicaid State Plan Amendment public notice and draft pages as viewed on the Mississippi Division of Medicaid website.

1. Page 1, Item 1.C. Reimbursement for 340B covered entities. Could you please explain line 3: Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.
2. Page 3, Item 5. What is the intent under availability of the SPA at each county health department?
3. Page 4, Attachment 4.19-B, page 12-a: reimbursement is described under EPSDT, which is the same language as in earlier pages of the document. How is EPSDT being singled out in the attachment similar/different (or does it impact) language in the previous 3 pages which does not include language for EPSDT?

Thank you and kind regards.

January 23, 2017 2:21 PM

Patti Hawkins
North MS Medical Center

We have read the SPA for pharmacy reimbursement and I think understand the changes in POS, and one of our questions is concerning the 340b entity language. I understand that the reimbursement rates and model has to be defined by the state Medicaid program to comply with the federal rule. Is the 340b language in the SPA specific for usage and claims filed through POS pharmacy systems at 340b entities?
We are trying to assess the impact if any to hospital outpatient drugs going through the medical benefit and OPPS methodology for hospital outpatients (non pharmacy or POS)

January 24, 2017

Mississippi Hospital Association
Medicaid Advisory Committee Meeting

What is included in the proposed pharmacy SPA? Interested in 340B details as budget projection numbers seem low if all 340B is included.

1/26/2017

Memorial Hospital at Gulfport
Brain Clark, PharmD, Manager,
Outpatient Pharmacy Services
Gulfport, MS

POS Pharmacies: Most 340B entities that own a POS pharmacy do not determine 340B eligibility at data entry. 340B claims qualifications are so complex that most use a 3rd party vendor to qualify claims retrospectively. So, it's not possible to charge 340 AAC at the time of dispensation to any 3rd party payer. Even if a pharmacy is low volume enough to determine 340B eligibility manually at data entry, why would they continue to carve-in Medicaid claims? Medicaid is completely taking away the 340B savings from the entity. Medicaid will force most 340B covered entity POS pharmacies to start carving-out Medicaid patients. This means that bot MS Medicaid and the Entity are now missing out on 340B discount savings. As a reminder, the intent of the 340B Program is to permit covered entities ''to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' H.R. REP. No. 102–384(II), at 12 (1992). Wouldn't it be much more prudent to work with Mississippi's 340B covered

entities to devise a plan that would mutually benefit both Medicaid and the entities? There are examples out there in other states where Medicaid and the entities share 340B savings. A process that allows for the sharing of savings is much more attractive to an entity compared to a plan that completely takes it away. If a 340B POS pharmacy begins to carve-out Medicaid from their 340B program, Medicaid gains nothing.

Physician Administered Drugs: Hospital software systems (i.e. Epic, Cerner, etc.) do not typically have placeholders for 340B AAC. You can't simply flip a switch and start charging 340B AAC. The programing and logistics of making such a change would be extremely costly and time consuming. Once active, these changes would continue to consume entity resources for ongoing maintenance and upkeep.

Physician Administered Drugs: Why would Medicaid expect anyone to be paid at AAC? The actual cost of administering a drug far exceeds what is paid to the wholesaler. If I understand correctly, Medicaid wants to pay entities that serve a disproportionately high volume of un or under-insured patients at a dollar amount less that what it cost to procure, store and administer the drug.

Physician Administered Drugs: Does this apply only to drugs charged independently of an infusion or procedure charge?

Physician Administered Drugs: Please specify exactly when and where 340B AAC is expected to be used. There is no room here for someone to assume any intent. Entities need it spelled out explicitly so as to have the same understanding. As the SPA currently reads, people have interpreted it differently.

1/26/2017

North Mississippi Medical Center
340B Program Coordinator
Patti Hawkins, PharmD,
Tupelo, MS

1. What are the specifics on the proposed claims submission for hospital outpatient claims that have been being paid under the OPPS logic?
2. Will drugs currently 'bundled' and not paid separately under the OPPS logic now be reimbursed even if at ACC?
3. Is there an additional reimbursement or dispensing fee or admixture fee allowance for agents requiring special admixture or handling other that ACC?
4. If a site carves out, will there be any change in claims submission requirements?
5. Will the Managed Medicaid plans be able to demand the same reimbursement model?
6. Does this policy apply to hospital dispensed physician administered drugs?

1/26/2017

BMHCC
Jillian Foster,
Admin-System Pharmacy
Memphis, TN

We have read the proposed pharmacy reimbursement document. We understand it is intended for point of sale retail pharmacies. Regarding 340b, we bill Medicaid for our outpatient infusions. Do we need to change anything about our billing practices?

January 30, 2017

Hello Mrs. Wilson
I am an employee with a Pharmacy Benefit Manager (PBM). I am in review of the SPA 17-0002 and seeking clarification on the following two drug reimbursements for Section I.:

D. Drugs acquired via the Federal Supply Schedule (FSS) – Ingredient cost based on AAC plus a professional dispensing fee of $11.29.

Q #1. Is there a file to supply the Federal Supply Schedule? Or is this self-reported by the pharmacies?
Q #2. Does the drug reimbursement apply to Outpatient pharmacies?
Q #3. Does the AAC definition apply: 1. NADAC or 2. WAC + 2% when no NADAC or 3. U&C ?

E. Drugs acquired at Nominal Price (outside of 340B or FSS) – Ingredient cost based on AAC plus a professional dispensing fee of $11.29.

Q #1. Where may I find the definition for Nominal Price.
Q #2. Is there a file to supply the Nominal Price? Or is this self-reported by the pharmacies?
Q #3. Does the drug reimbursement apply to Outpatient pharmacies?
Q #4. Does the AAC definition apply: 1. NADAC or 2. WAC + 2% when no NADAC or 3. U&C ?

Sincerely
Kym

Kymberly McFarland
Director, Pharmacy Network Operations

5 River Park Place E, Suite 210 | Fresno, CA 93720

January 31, 2017

Patti Hawkins, PharmD
North Mississippi Medical Center

I reviewed the latest posting of SPA 17 0002 where the last paragraph describing 340b has been removed. Does this serve as clarification that the SPA and 340b language will be applicable to POS pharmacy programs enrolled as Medicaid network pharmacies and not to hospital outpatient or facility services billed through the medical and paid under the OPPS fee schedule?

Thank you

February 9, 2017

Brian Clark, PharmD
Memorial Hospital at Gulfport
4500 13th Street,
Gulfport, MS 39501

Re: SPA 17-0002 Pharmacy Reimbursement

- 1.C. POS Pharmacies- Reimbursement for 340B covered entities
    - Most 340B entities that own a POS pharmacy do not determine 340B eligibility at data entry. 340B claims qualifications are so complex that most use a 3rd party vendor to qualify claims retrospectively. So, it's not feasible to charge 340B AAC at the time of dispensation to any 3rd party payer. Medicaid should work with covered entities to devise a process that will allow pharmacies to be compliant with both HRSA/OPA's 340B rules and SPA 17-002.
    - It's important for Division of Medicaid to understand the process that entities must follow to verify a claim qualifies for 340B. This process describes how most POS pharmacies owned by a 340B entity qualify claims.
        - Claim is processed at POS at the pharmacy's U&C pricing. Patient pays their set copay as defined by their 3rd party payer.
        - Pharmacy sends all processed claims to their TPA (usually a daily file upload after close of business).
        - Entity sends all patient encounter files to the TPA either once daily or through a live ADT feed. The encounter file includes the location and time stamp of the encounters.
        - Entity maintains an updated file of all eligible locations. Any changes to the file are provided to the TPA and are updated with HRSA.
        - Entity maintains an updated qualified provider file and provides the file to the TPA on a defined timeline.

        - TPA takes each claim and scrubs it against the provider file to ensure it matches a provider who was an approved provider on the date the prescription was written. If the claim passes, it is checked to verify that the electronic prescription was generated from an eligible encounter for that patient at an eligible and registered location. If the prescription was not an electronic prescription, the date the prescription was written is compared to that patient's encounters. If there is an eligible encounter for that patient at that time at an eligible and registered location, it is approved. That drug's dispensed quantity is added to the drug's accrual file. If any one step of this process fails, the prescription is deemed non-qualified.
        - Due to the GPO prohibition for DSH hospitals, all drugs are purchased at WAC pricing. Only when enough qualified 340B prescriptions have accrued to equal an entire package size of a drug will it be re-purchased on 340B. Simply being 340B qualified does not automatically signify that the drug was actually purchased by the pharmacy on 340B.
    - How does the Division of Medicaid expect 340B entity owned POS pharmacies to indicate that a claim is 340B? As you can see in the details above, claims are not processed as 340B at the time of claim processing.

February 10, 2017

Bruce J. Toppin, Vice President/General Counsel, Corporate Secretary
North Mississippi Health Services
830 South Gloster Street
Tupelo, Mississippi 38801

RE: State Plan Amendment 17-0002 of Mississippi Medicaid effective April 1, 2017

Dear Ms. Wilson:

Please accept this letter as comments and objections on behalf of North Mississippi Health Services, Inc. itself and the owned and operated hospitals (collectively, "NMHS") listed below:

North Mississippi Medical Center, Inc.
Pontotoc Health Services, Inc.
Clay County Medical Corporation
Webster Health Services, Inc.

Background: The SPA 17-0002 ("SPA") was published for comment on January 11, 2017. Most of the SPA addresses the point of sale ("POS") pharmacy programs under the Pharmacy Division of Mississippi Medicaid. A portion of the SPA addresses the reimbursement for 340B hospitals in the POS portion of the document. Specifically,

statement on page 12a.S was directed at 340B hospitals and physician administered drugs. The Amendment has created confusion among the hospital community. It is not clear if the Amendment was intended to apply to drugs currently administered at hospitals and paid under the OPPS fee schedule. The Department of Medicaid ("DOM") has given advice and clarification that it was the intent; however, on or about January 30, 2017, page 12a.5 was removed from the SPA and a revised SPA was published on the DOM website. DOM has not provided Hospitals with received confirmation that this removal does in fact exempt facility or physician administered drugs from the 340B directive and now will apply only to outpatient drugs billed by Medicaid Pharmacy providers through POS. As revised, the SPA is arbitrary and capricious. The attestation letters received this week from Medicaid still include language applying claim filing instructions for physician administered and facility outpatient claims on UB and HCFA forms. This is contributing to the already existing confusion. We have requested clarification of this as well.

Assumption #1- Hospitals billing under OPPS for outpatient drugs will not be exempt

1. The immediate impact of a change in reimbursement from the current Medicaid fee schedule to an actual acquisition cost ("AAC") plus no dispensing fee or allowance would result in a financial loss and undue burden on 340B participating hospitals already providing a high level of uncompensated care. Depending on the expansiveness of the final SPA, NMHS will absorb costs in the range of $420,000 - $1,200,000 in order to continue to provide the same level of service for patients insured by regular and managed Medicaid. It is worth noting that under OPPS, most drugs are already not paid separately, but bundled as part of an administration fee. Current Medicaid reimbursement scarcely covers allocated costs and overhead associated with treatment. Thus, the proposed change will directly impact patient access, as well as the breadth and depth of services offered to this vulnerable population.

2. Administrative burden to include AAC on Hospital Claims. As stated by numerous hospital entities, there are no financial systems that are designed to accommodate inclusion of AAC, as these systems are based on HCPC coding of drugs and not integrated with purchasing systems. If required to include AAC, the administrative burden of manually inputting the information will be unreasonable. It also creates the potential for error and would be impractical for facilities to undertake, leaving the only option for 340B entities to carve out Medicaid and begin buying these same drugs at WAC price; thereby, increasing the expense to the facilities that qualified for 340B as a result of serving a high proportion of disadvantaged patients. This is contrary to the intent of the 340B Disproportionate Share Hospital (DSH) program, which allows hospitals with a disproportionate number of Medicaid and uninsured patients to obtain financial relief from high drug costs.

3. Other unanswered questions and issues for consideration. If a proposal is enacted to apply AAC to physician administered drugs for facilities currently billing under the Medicaid OPPS fee schedule, would the currently bundled 'N' status drugs become eligible for cost reimbursement? If not, then 340B hospitals would be penalized twice in the reimbursement logic.

The assumption that AAC of product reflects the cost associated with provision of physician administered drugs is arbitrary and unreasonable. Also, the payer restrictions, audits, and prior authorization requirements further add to the cost of providing care to Medicaid members.

Assumption #2- The 3408 reimbursement language remaining in the SPA 17 0002 applies only to POS

1. If the revised SPA is applied only to POS pharmacy services in 340B entities, then the area impacted would be the drugs billed and dispensed to qualified 340B home infusion and specialty pharmacy patients. If the SPA allows managed plans to implement the same reimbursement structure of only reimbursing cost plus a dispensing fee, participating hospitals will not be able to cover allocated costs. Additionally, if the reimbursement structure is allowed to be applied to managed Medicaid, barriers imposed such as prior authorizations, excessive audits, etc., from the managed programs will apply, and the administrative cost and burden to the 340B entity will be increased. Thus, there will be no incentive for 3408 entities to remain carved in; thereby, effectively increasing the cost to the entity and the Medicaid program.

2. If the 3408 entity carves out, it will be contradictory to the intent of the 3408 program which was "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." It penalizes hospitals providing care to a high number of Medicaid patients.

3. There is not a federal requirement that state Medicaid programs reimburse AAC, only that state Medicaid programs need to define 3408 reimbursement. There are other state models where covered entities and Medicaid share in savings garnered through using 3408 contract purchases, which is more congruent with the intent of the 3408 program. Consequently, NMHS suggests that the DOM review these models for adoption.

4. There is language in the SPA directed specifically to 'specialty' pharmacy and drugs. As a health system that provides comprehensive services to all patients, NMHS would like further definition of what is considered a 'specialty' drug. NMHS also requests clarification that health systems providing specialty drugs to patients, in their comprehensive care model, are not disadvantaged or excluded through this SPA or future programs.

5. Again, NMHS is very concerned with these reductions in reimbursement being allowed to extend into the Managed Medicaid market (Magnolia and UHC) as the barriers and extensive administrative burden in these plans are already very costly to providers.

6. For POS pharmacies, these changes will require system alterations. NMHS needs the EDI requirements.

7. It would be advantageous to all parties to hold a 3408 entity stakeholder meeting with the DOM to facilitate dialogue and clarify the provisions of the SPA. The SPA, in its current state, creates barriers for providers to participate in the Medicaid program.

Thank you for the opportunity to express concerns and provide input. If you have any questions, or if you require any additional information, feel free to contact me at your convenience.

February 10, 2017

T. Richard Roberson, General Counsel, Vice President for Policy and State Advocacy
Mississippi Hospital Association
116 Wood Green Crossing
P.O. Box 1909
Madison, MS 39130-1909

Re: Proposed Changes in Pharmacy Reimbursement

Dear Dr. Dzielak:

Thank you for the opportunity to provide input regarding the proposed changes in Medicaid pharmacy reimbursement. We are aware that the Centers for Medicare and Medicaid Services ("CMMS") has implemented reductions in the Federal Upper Limits for prescription drugs; however, we are also aware that CMS is allowing states the flexibility to choose their reimbursement methodology for ingredient costs for prescription drugs, so long as this methodology more closely aligns to the actual price paid to acquire the prescription drugs, as well as the reimbursement for professional dispensing fees.

In its letter to State Medicaid Directors dated February 11, 2016, CMS provides states with various reimbursement methodologies as examples to consider. Based on information provided at Medicaid's Pharmacy Stakeholders Meetings, your agency considered various options for the ingredient cost reimbursement methodology, including, State Actual Acquisition Cost ("AAC"), National Average Drug Acquisition Cost (''NADAC"), and published pricing benchmarks, e.g., Wholesale Acquisition Cost ("WAC"). Estimated reimbursement for each option was also provided. In one presentation, the reimbursement estimates ranged from a high of $634.1 million to a low of $618 million.

CMS has acknowledged that the State has options in choosing its methodologies. Medicaid also recognized this by presenting various methodologies for reimbursement at the stakeholder meetings. Because there are various options, we contend that the Mississippi Legislature must decide which reimbursement methodology is implemented. This position is based on the plain language of Section 43-13-117(D) which prohibits the agency from changing payment methodologies for pharmacy services except as required by federal law.

This position is also supported by the holding of the Mississippi Supreme Court in Mississippi Independent Pharmacists v. Medicaid, (Miss. 2008).

Additionally, on January 20, 2017, President Trump signed an Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal. The Executive Order directs the Secretary of Health and Human Services and the heads of all other executive departments and agencies with authorities and responsibilities under the Patient Protection and Affordable Care Act (the "Act") to exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a cost, fee, tax, penalty or regulatory burden on healthcare providers (among other individuals and entities). We believe that the federal regulation Medicaid is relying upon as the basis of its proposed State Plan Amendment imposes a cost on healthcare providers and, would not be enforced by the Secretary of Health and Human Services and/or the Centers for Medicare and Medicaid Services pursuant to the Executive Order. Therefore, the underlying federal requirement is not enforceable and the proposed rule is not required.

Further, we do not believe that Medicaid has considered the amount of time and the costs of system changes that pharmacy providers, particularly hospital pharmacies, will be required to make as a result of these changes. Current billing systems do not consider AAC in its coding. Including such, particularly for 340B drugs would create an administrative burden. The estimated economic impact appears to only consider the reduction in pharmacy spending. We would ask that the agency estimate the costs involved to timely implement these system changes in order to comply with an April 1, 2017 effective date.

Thank you for considering these comments. It is imperative that we work together to sustain sufficient payments which maintain access to care for Medicaid beneficiaries. We look forward to working with you and other stakeholders regarding ways to improve healthcare outcomes for Medicaid beneficiaries.

February 13, 2017

Todd Dear, PharmD, BCPS
Director - Pharmacy Services
University of Mississippi Medical Center

UMMC projections of the financial impact of these changes as stated approach upwards of 2 million dollars annually for our organization. Our comments seek to help achieve compliance with required federal regulations including the Covered Outpatient Drug Final Regulation for Fee for Service Medicaid patients while reducing the impact on providers.

1C. Reimbursement for 340B covered entities:

Please clarify that this guidance is for Retail Point of Sale operations only.

The current plan states that entities will bill Actual Acquisition Cost of 340B products at the price at which the covered entity paid the wholesaler or manufacturer. **We advocate that Medicaid allow 340B providers to bill claims at their usual and customary rates**. There are many administrative and compliance challenges that would prohibit a provider from being in compliance with AAC billing as stated by the SPA.

- Providers would be forced to maintain a separate pricing file for 340B drugs billed to Medicaid, which could cause unintentional errors due to multiple systems having to be utilized.
- These prices can change throughout the quarter, and this would require hospitals to constantly monitor and update their 340B pricing file to ensure accurate billing and compliance.
- Often stock is purchased at multiple price points within the same pharmacy. In addition for institutions with multiple pharmacies. The ability to maintain multiple 340B pricing files is limited at best. While UMMC is able to identify 340B claims at point of service (POS), identification of eligible 340B claims as POS is not possible for many providers.
- Allowing entities to bill at usual and customary rates alleviates the necessity for 340B identification prior to adjudication.

In light of the above, **we encourage MS Medicaid to establish a fee schedule that approximates the 340B ceiling price** rather than requiring AAC billing as currently stated. The 340B ceiling prices are known to the states based on their access to the average manufacturer price (AMP) and unit rebate amount (URAs) through the drug data reporting (DDR) system. The formula for calculating the 340B ceiling price is generally defined in section 340B(a)(1) of the PHSA as AMP minus the URA, and these data are available for states in DDR. In the event that reimbursed costs are less than entities acquisition costs, we recommend an avenue for actual ingredient reimbursement by invoice.

We encourage MS Medicaid to consider the significant additional costs associated with dispensing 340B medications. Regulatory, compliance, eligibility screening, and WAC purchasing costs (DSH 340B entities) should be considered when developing methodologies that ensure pharmacy providers, including 340B entities, are reimbursed adequately for provision of pharmacy services. **We recommend that 340B dispensing fees be set at a higher rate to compensate for these additional costs not experienced by non-340B entities.**

We recommend that covered entities continue to be free to negotiate retail reimbursement rates directly with Managed Care Organizations. The Covered Outpatient Drug final rule and its requirements are specific to FFS Medicaid recipients only. We recommend that processes be put into place that exclude dispensed 340B drugs from rebate collection without dictating reimbursement policies.

1F. Specialty drugs not dispensed by a retail community pharmacy and dispensed primarily through the mail.

We ask for clarification on how MS Medicaid will define specialty medication. Timely access to specialty medications is crucial for patients and limited. We ask that all willing providers be able to participate in dispensing functions.

We ask that all willing providers be able to collect the higher stated dispensing fee (61.14) to help compensate for the considerable inventory cost required to keep these high cost products readily available. In addition, increased cognitive services is required when dispensing these products to patients.

The overall impact analysis with the current proposed rule changes demonstrates significant negative financial impact to providers who are serving an already vulnerable patient population. Continued decline in reimbursement for underserved patient populations will continue to erode the ability for providers to supply needed services.