



SHO# 16-001
Affordable Care Act # 37

**RE: Implementation of the Covered
Outpatient Drug Final Regulation Provisions
Regarding Reimbursement for Covered
Outpatient Drugs in the Medicaid Program**

February 11, 2016

Dear State Medicaid Director:

This letter is being issued to provide guidance to the states concerning implementation of the Covered Outpatient Drug final rule with comment (CMS-2345-FC) (81 FR 5170) published on February 1, 2016, concerning final regulations pertaining to reimbursement for covered outpatient drugs in the Medicaid program. It outlines the key changes that states need to address when determining their reimbursement methodologies, including the revised requirement in 42 CFR §447.512(b) for states to reimburse at an aggregate upper limit based on actual acquisition cost (AAC) plus a professional dispensing fee established by the agency; the implementation of the Affordable Care Act federal upper limit (FUL); and requirements for the 340B entities, 340B contract pharmacies, Indian Health Service (IHS), Tribal, and Urban Indian Organization (I/T/U) pharmacies. Also, this letter addresses the requirement for states to review both components of their total pharmacy reimbursement methodology when proposing changes to either the ingredient cost or the professional dispensing fee for all reimbursement methodologies to ensure that total reimbursement to the pharmacy provider is in accordance with the requirements of section 1902(a)(30)(A) of the Social Security Act (the Act). Lastly, this letter provides the information that states must include in a state plan amendment (SPA) relating to any proposed changes in reimbursement and the timeframe established for states to comply with the new requirements.

Background

States generally reimburse pharmacies for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries based on a two-part formula consisting of the ingredient cost of a drug and a professional dispensing fee. States have flexibility to determine reimbursement amounts, consistent with applicable statutory and regulatory requirements. These reimbursement amounts are subject to review and approval by the Centers for Medicare & Medicaid Services (CMS) through the SPA process.

Outlined below are the major reimbursement provisions of CMS-2345-FC and important clarifications for states as they submit SPAs to implement these provisions.

Actual Acquisition Cost (AAC) for Drug Reimbursement

In accordance with the Affordable Care Act and requirements of §447.512(b) of the final regulation, states' reimbursement for ingredient costs for brand and certain multiple source drugs (that do not have a FUL calculated), will be established as an aggregate upper limit based on AAC, as opposed to an estimated acquisition cost. AAC is defined at §447.502 of the final regulation as the agency's determination of the pharmacy providers' actual prices paid to acquire drugs marketed or sold by specific manufacturers. CMS believes that changing this definition of ingredient cost reimbursement to AAC will provide a reference price consistent with the dictates of section 1902(a)(30)(A) of the Act.

As discussed in Section II.J. (81 FR 5290) of the preamble for the final rule with comment, a state can implement an AAC model of reimbursement based on various pricing methodologies. Below are some examples.

1) States may develop an AAC model of reimbursement that is derived from a state survey of retail pharmacy providers' pricing. Several states have already implemented a state survey to develop an AAC model of reimbursement, and may continue to use such surveys to implement the AAC requirement provided the surveys align with the aggregate upper limit based on AAC as discussed in section II.J. of the preamble for the final rule with comment (81 FR 5290).

2) States may submit a SPA that uses a national survey, such as the National Average Drug Acquisition Cost (NADAC), to establish their AAC model of reimbursement. The NADAC files, which are published on a monthly basis and updated weekly, are designed to represent a national pricing methodology based upon a simple average of voluntarily-submitted retail pharmacy acquisition costs for most covered outpatient drugs. The files are derived by surveying randomly selected, retail community pharmacies nationwide on a monthly basis. CMS began posting the NADAC files in draft on the Medicaid.gov website in October 2012 and finalized the files in November 2013. Further information on the NADAC can be found on the Medicaid.gov website at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html>.

3) States may use published compendia prices, such as the wholesale acquisition cost, to establish an AAC model of reimbursement. However, published prices may not reflect the actual prices paid by retail pharmacies; therefore states will be expected to make adjustments to these benchmarks to reflect discounts and other price concessions that are commonly obtained by retail pharmacies. Furthermore, if a state chooses this approach, the burden is on the state in its SPA submission to demonstrate, with a survey or other reliable data that the proposed reimbursement based on published compendia pricing is consistent with the aggregate upper limit based on AAC as discussed in section II.J. of the preamble for the final rule with comment (81 FR 5290).

4) States may submit a SPA that establishes a reimbursement methodology using average manufacturer price (AMP)-based pricing. The state can determine the relationship between AMP and factors such as the wholesaler markup, which covers the cost of distribution and other service charges by the wholesaler, in order to determine a reasonable reimbursement that would appropriately compensate pharmacies in accordance with the requirements of the final

regulation. CMS notes that section 1927(b)(3)(D)(i) of the Act states, in part, that AMP may be disclosed as the Secretary determines it to be necessary to carry out section 1927 of the Act. Further, section 1927(b)(3)(D)(iv) of the Act permits disclosure of AMP data to states to carry out Title XIX; however, CMS reminds states that such information is confidential and should not be disclosed in a form which discloses the identity of a specific manufacturer or wholesaler, or the prices charged for drugs by the manufacturer or wholesaler, except for certain exceptions. CMS believes that these provisions, when read together, permit states to use AMP-based pricing for purposes of pharmacy reimbursement; however, we further note that any disclosure concerning AMP must be addressed by the state during the SPA submission process. During the SPA process, the state must demonstrate how such disclosure of the AMP-based prices is consistent with the confidentiality requirements set forth by the statute and other applicable federal regulations and statutory requirements.

The state should include in its SPA the reimbursement methodology that it will use to establish its AAC reimbursement model, as well as how the state will obtain and update that methodology. The state should also specify in its SPA any alternative methodology that will be used in the case where a pricing methodology that represents an AAC model of reimbursement is not available for a specific drug for a specific time period.

Reimbursement for 340B covered entities, 340B contract pharmacies, Indian Health Service (IHS), and IHS, Tribal, and Urban Indian Organization (I/T/U) pharmacies

In accordance with the requirements in §447.518(a)(2), the state's payment methodology for drugs dispensed by 340B covered entities, 340B contract pharmacies, and I/T/U pharmacies must be in accordance with the definition of AAC in §447.502 of the final regulation. For drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price. If the drug is purchased outside the 340B program, the reimbursement should not exceed the provider's AAC.

For drugs purchased through the Federal Supply Schedule (FSS), reimbursement should not exceed the FSS price. States that pay IHS and Tribal providers through encounter rates can continue to pay at that rate since this will satisfy the requirements in §447.518(a)(2), which specify that the state's payment methodology for these entities must be in accordance with the definition of AAC in §447.502 of the final regulation.

In addition, in accordance with the requirements in §447.518(a)(1) of the final regulation, SPAs must comprehensively describe the payment methodology for reimbursement of drugs dispensed by 340B entities, 340B contract pharmacies, and I/T/U pharmacies, in accordance with the definition of AAC, as well as the payment methodology for how such entities are reimbursed, including stating if encounter rates will be used for IHS and Tribal providers. The state should include in its SPA the reimbursement methodology that the state plans to use to establish the AAC reimbursement model – e.g., state survey, discounted published compendia pricing data, 340B ceiling price, etc., – and state how this methodology will be incorporated into its pharmacy reimbursement policies.

The SPA should also specify the alternative methodology that will be used by the state for reimbursement in the case where a pricing methodology that represents an AAC model of reimbursement is not available for a specific drug for a specific time period.

States are also encouraged to evaluate their professional dispensing fees for 340B entities, 340B contract pharmacies, and I/T/U pharmacies. See discussion of professional dispensing fees below.

Affordable Care Act FULs for Multiple Source Drugs

In accordance with section 1927(e) of the Act, as amended by section 2503(a) of the Affordable Care Act, and the requirements in §447.514(b)(1) and (2) of the final regulation, we established an exception to the FUL calculation, which allows for the use of a higher multiplier to calculate the FULs based on acquisition costs for certain multiple source drugs. Specifically, in the final regulation, CMS finalized an exception to calculating the FUL at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, in instances where that amount is less than the average retail community pharmacies' acquisition cost for such drugs as determined by the most current national survey of such costs (e.g., NADAC). In situations where the FUL is less than the average retail community pharmacies' acquisition cost, CMS will establish the FUL using a higher multiplier so that the FUL amount would equal the most current average retail community pharmacies acquisition cost as determined by the most current national survey of such costs.

CMS notes that where a multiple source drug has multiple acquisition costs calculated per unit CMS will not publish a FUL for that drug, as we consider those drugs to not have a one-to-one corresponding acquisition cost to FUL for comparison. We may consider future rulemaking to propose a methodology to calculate a FUL for those multiple source drugs. In addition, where a multiple source drug has no corresponding acquisition cost available for comparison, CMS will not publish a FUL for those drugs. Further information on these drugs can be found in the Methodology and Data Elements Guide, which will be published on the Medicaid.gov website at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html>.

In accordance with §447.514(b)(1) of the final regulation, the upper limit for reimbursement continues to be established as an aggregate upper limit; therefore, states are not required to use the FUL amounts to reimburse for individual claims. A state has flexibility in determining reimbursement for multiple source drugs subject to the FUL, provided that total reimbursement for the annual period does not exceed the aggregate upper limit reimbursement and is consistent with the approved state plan. Alternatively, states can use another methodology such as the NADAC or their state maximum allowable cost for calculating payment, provided that the methodology is consistent with upper limit requirements. States are responsible for submitting a SPA demonstrating compliance with applicable requirements in the final rule with comment if the state proposes any change relating to pharmacy reimbursement as they implement the provisions of § 447.514. In accordance with the requirements in §447.518(b), states are required to make findings and assurances for their aggregate expenditures.

In accordance with sections 1927(e)(4) and (5) of the Act, CMS will establish a FUL for each multiple source drug for which the Food and Drug Administration has rated at least three or more drugs therapeutically and pharmaceutically equivalent (A-rated), regardless of whether all such additional formulations are rated as such.

All covered outpatient drugs with the same ingredient, route, strength, and dosage form are included in a FUL group, which includes both prescription and over-the-counter drugs. The published FUL file will include a comprehensive worksheet listing all of the national drug codes (NDC) at the package size (NDC-11) level. However, only those drugs that appear on that worksheet as A-rated are included in the calculation of the FUL. Further, the FUL will only apply to those A-rated drugs. Further information on the Affordable Care Act FULs, including an updated Methodology and Data Elements Guide, will be published on the Medicaid.gov website at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html>.

CMS published the first draft FUL files calculated in accordance with the Medicaid Covered Outpatient Drug final rule with comment (CMS-2345-FC) on the Medicaid.gov website (<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/federal-upper-limits.html>) on January 28, 2016 and CMS plans to publish another draft FULs file at the end of February. The final Affordable Care Act FULs will be published in late March 2016 and will be effective on April 1, 2016 to coincide with the effective date of the final rule with comment. States will have up to 30 days from the April 1, 2016 effective date to implement the FULs. Once the final regulation is effective, CMS will remove the FULs that are currently in effect, which were last updated on September 25, 2009. Further, CMS will provide monthly notification to the states via the “Medicaid Prescription Drug Policy & Reimbursement Updates” listserv when the draft Affordable Care Act FUL files are updated and when they are finalized. In addition, CMS will continue to issue these monthly notifications for the first six months after the finalization of the FULs. To sign up for our listserv, please click on the following link, https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_589.

CMS clarifies that as of the date that the agency publishes the Affordable Care Act FULs using the revised methodology in accordance with §447.514(b)(1) and (2) of the final regulation, we will no longer be calculating the three-month rolling average FUL.

Professional Dispensing Fee

In the final regulation, the revision of the term “dispensing fee” to “professional dispensing fee” at §447.502 is designed to reinforce our position that the dispensing fee should reflect the pharmacist’s professional services and costs to dispense a drug to a Medicaid beneficiary. While CMS defines this term, we do not intend to mandate a specific formula or methodology that states must use to determine the professional dispensing fee. However, states need to ensure that pharmacy providers are reimbursed adequately for their professional services consistent with the requirements of the final regulation. Pharmacy provider reimbursement rates should be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, in accordance with section 1902(a)(30)(A) of the Act.

Therefore, in compliance with the requirements codified at §447.518(d) of the final regulation, states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement to ensure that total reimbursement to the pharmacy provider is calculated in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate data, such as a state or national survey of retail pharmacy providers or other reliable data other than a survey, to support any proposed changes to either or both of the components of the reimbursement methodology. CMS will review the survey/data that a state submits on a case-by-case basis to ensure that the reimbursement proposed aligns with the state's cost to dispense as documented in the survey/data. States retain the option to adjust the professional dispensing fee for provider type or services rendered such as special packaging or delivery.

Compliance – SPA Submission

CMS realizes that states may need time to revise their Medicaid state plans to accommodate requirements of provisions §447.512(b), 447.518(a), and 447.518(d) of the final regulation. Therefore, we have decided to allow the states four quarters from the effective date of the final rule with comment, which is April 1, 2016, to revise their state plan and submit a SPA with an effective date no later than April 1, 2017 to comply with these provisions noted above. CMS believes this compliance date will give states sufficient time to implement any changes that are required to revise drug ingredient costs as well as professional dispensing fees. CMS reminds states that they must comply with the public notice provisions set forth in §447.205. States must also comply with requirements to solicit advice prior to submission from I/T/U providers pursuant to section 1902(a)(73) of the Act.

CMS looks forward to our continuing work together to implement the provisions of the final regulation. Questions regarding Medicaid drug provisions can be submitted through the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov or may be directed to John Coster, Director, Division of Pharmacy, Disabled and Elderly Health Programs Group, at (410) 786-1121.

Sincerely,

/s/

Vikki Wachino
Director

cc:

National Association of Medicaid Directors

National Academy for State Health Policy

American Public Human Services Association

National Governors Association

Council of State Governments

Association of State and Territorial Health Officials