

340B Pharmacy Pricing 2011 Public Comments

<u>Numb:</u>	<u>Date/ Commentor:</u>	<u>Comment:</u>	<u>Response:</u>
1.	10/19/2011 John McDonald, CEO AACHC	<p>The AHCCCS program has approached the 340B Community Health Centers (CHC) providing services to Medicaid eligible outpatients with the plan to change the reimbursement model to one tied to the entity's drug acquisition plus cost of dispensing (COD) designed to "cover" the organization's cost while removing any positive revenue stream. This proposed AHCCS ruling is being done in conjunction with an effort to have Arizona participate in the federal rebate program and associated efforts to contain AHCCCS programmatic costs.</p> <p>The AHCCCS reimbursement change, while intended to cover 340B entity costs, will not do so at the reimbursement rate of \$8.75 for the vast majority of CHC 340B pharmacies. The average cost of dispensing for AACHC 340B pharmacies is \$12.28. The COD rate of \$8.75 will have the unintended consequence of reducing the ability of organizations to continue their 340B programs and in some cases cause closure of these pharmacy services. The Grant Thornton National Cost of Dispensing (COD) Study Final Report January 26, 2007 referred to by AHCCCS to determine the \$ 8.75 rate for AACHC pharmacies found that the cost is significantly higher. The actual average pharmacy cost of dispensing for Medicaid in the study is \$12.81. The \$12.81 number is reflective of 2006 data</p>	<p>The Grant Thornton study is one among several information sources viewed by AHCCCS. Section 7 of the preamble has been revised to clarify this.</p> <p>The Cost Of Dispensing (COD) cited by the commenter is identified in that study as the "non-weighted average per pharmacy." AHCCCS has established a per-prescription dispensing fee and believes that, for purposes of comparison to the proposed dispensing fee, a per-prescription statistic is more relevant. AHCCCS also believes that, given the likelihood of outliers in the type of data studied, median is the better measure of central tendency.</p> <p>In viewing the Grant Thornton study, as well as other studies presenting similar information, AHCCCS gave its attention to the median COD per prescription.</p>

as reported in 2007 Grant Thornton Cost of Dispensing Study. Adjusted for CPI physician service annually for 2011 the COD would be \$14.82.

We would encourage AHCCCS to look at possible ways to expand the availability of 340B services including a more realistic COD reimbursement and possibly shared profits rather than policies that may have the unintended consequence of limiting availability of 340B services making access more challenging and possibly reducing some longer term cost savings to the program.

2. 10/21/2011
Dave
Dederichs,
Director
Government
Affairs
Express
Scripts, Inc

Article 7 Section B. Pharmacy services and Section C. FQHC Pharmacy reimbursement. (340B entity)

Currently, there is not a system to identify 340B claims. The definitions of these fields changed recently at the last NCPDP workgroup to state that the fields were only applicable to FFS Medicaid or when required by law or regulation. For this reason, we are concerned that if the State does not mandate these fields be populated, our ability to appropriately identify all 340B drugs is limited. Those fields are:

- Basis of Reimbursement Determination field (522-FM) – value of 12 indicates drug was accessed at 340B prices
- Basis of cost determination code (423-DN) – value of 8 indicates 340B claim
- Compound Ingredient Basis of Cost Determination (490-UE) – value of 8 indicates 340B claim.

Express Scripts cautions the state about the impact of retroactive

In the proposed rule on p.8, 2 d., it states “The 340B drug claim identifier shall be consistent with claim instructions issued and required by AHCCCS to identify such claims”. AHCCCS will communicate prescription claims submission requirements, including, but not limited to, the “340B Identifier” and the “Ingredient Cost Submitted” fields to the AHCCCS FFS PBM and to AHCCCS Managed Care Contractors.

AHCCCS recognizes that contractors and subcontractors may require a minimum of 30 days to facilitate and implement the rule requirements and will ensure timely notification is provided. The listing of 340B entity pharmacies can be accessed at the HRSA/Office of Pharmacy Affairs website, www.hrsa.gov/opa/. The website contains a link to 340B entity database. AHCCCS will provide a monthly list of the FQHC/ FQHC Look-Alike pharmacies to the AHCCCS FFS PBM and AHCCCS Managed Care Contractors.

changes or changes that would result in less than 30 days for implementation. ESI would like to stress the importance of timely and prospective notification of list changes by the state.

Recommendation: Express Scripts recommends that the State prospectively maintain the list as necessary, and that updated lists be made readily available to all providers in a timely manner.

Please refer to the first paragraph above.

Express Scripts is concerned that pharmacies may not disclose their 340B acquisition costs per the requirement of this rulemaking. The proposed rule does not explain what data field should be used report the acquisition cost.

Recommendation The State should mandate the inclusion of the fields mentioned above (NCPDP transactions set) and require the submission of the 340B price in the Ingredient Cost Submitted fields.

3. 10/21/2011
William
Vanaskie,
Executive
VP/COO

The AHCCCS program has approached the 340B Community Health Centers (CHC) providing services to Medicaid eligible outpatients with the plan to change the reimbursement model to one tied to the entity's drug acquisition plus cost of dispensing

The state is permitted to collect rebates for prescription drugs dispensed to Medicaid eligible persons by a CHC if the drugs were not purchased through the 340B program. The Medicaid Act already requires full cost reimbursement for FQHCs and RHCs services, as defined in federal law, which are

Maricopa Integrated Health System (COD) designed to “cover” the organization’s cost while removing any positive revenue stream. This proposed AHCCS ruling is being done in conjunction with an effort to have Arizona participate in the federal rebate program and associated efforts to contain AHCCCS programmatic costs.

This change appears inconsistent with the original tenants of the 340B statutes and will effectively penalize those entities, especially qualified Community Health Centers, by not only eliminating a positive revenue source but in almost all cases turning this service into a revenue losing proposition. The consequences of this move are obvious. In order to continue to serve the medical needs of the Medicaid population, CHC's will need to cut prescription services in total or not secure the drugs under the 340B program and attempt to negotiate low acquisition costs that could then be covered by existing reimbursement rates. In either case the results will mean less rebates available to AHCCCS.

We believe this rule is short-sighted and will not result in the quantity of rebates the AHCCCS Program anticipates. Therefore, the change will be pointless. There are other alternatives that should be pursued if AHCCCS persists in reducing the cost of providing services to the Medicaid population.

provided to AHCCCS members. Those services do not include pharmacy services. With respect to pharmacy services, the Medicaid Act requires that states establish reimbursement rates that are consistent with efficiency, economy, quality of care, and access to care. AHCCCS believes that the reimbursement methodology described in this rule meets that standard. Federal courts have interpreted this requirement to mean that payment rates for pharmacy services must be reasonably related to the cost of the services. However, it does not require Medicaid agencies to cover the actual cost of pharmacy services provided in FQHCs, and FQHC Look-Alikes and 340B entity contracted pharmacies.

AHCCCS is mandated to participate in the federal rebate program. The intent of the 340B statutes was not to encourage entities to reap excessive profits from the Medicaid Program. AHCCCS does not expect to receive increased rebates since the proposed rule requires the entity to submit the actual acquisition cost for drugs subject to the 340B pricing file so that the savings will now be passed on to the State on the front end. The State will not be able to submit the utilization for these drugs for purposes of obtaining Medicaid rebates since AHCCCS will have obtained the discount on the front end.

4. 10/21/2011 AHCCCS’ proposed rule, as written, poses unworkable requirements on contract pharmacies. If left unmodified, the
Michael F.

On March 15, 2000, the Department of Health and Human Services, Health Resources and Services Administration, issued a

Smith, Senior Manager Karl Meehan, VP, Walgreens proposed rule could harm high-risk patient population, while providing little, if any, financial benefit to AHCCCS. The following concerns and considerations should be accounted for before a decision is made to proceed with the implementation of the proposed rule:

1. The proposed rule refers in several sections to ‘claims for drugs purchased under the 340B pricing program. The references imply the utilization of a prospective model whereby covered entities and their contract pharmacies dispense inventory already purchased at 340B pricing, and subsequently submit claims for these drugs. Walgreens uses a replenishment (retrospective) model for 340B claims, which is the prevalent industry model. Such model is operationally more efficient as well as more effective in preventing drug diversion and avoiding duplicate discounts. Pharmacy industry participants, including several State Medicaid agencies are using the National Council of Prescription Drug Programs (NCPDP) forum to develop a solution (described later in the proposed solution section of this letter) that is in line with the more commonly-used replenishment model. The proposed rule is at odds with the replenishment model, and creates a situation where entities and contract pharmacies that use this model are unable to meet the requirements set forth.
2. Section 7 of the preamble requires the agency to provide references to any study relevant to the rule that the agency reviewed and proposes to rely on its

Notice Regarding the Section 340B Drug Pricing Program— Program Guidance Clarification (Duplicate Discounts). “For appropriate Medicaid drug reimbursement procedures, the Health Resources and Services Administration (HRSA) refer the covered entity to its respective State Medicaid agency for guidance.”

AHCCCS is the state agency responsible for administering the Medicaid program for the state of Arizona. The proposed rule defines the 340B claims submission procedures for FQHC and FQHC Look-Alike pharmacies. (Note that the application of this methodology to 340B contracted pharmacies has been removed in the supplemental rulemaking). A covered entity may have a replenishment model or other contractual arrangement between the 340B entity and their contracted pharmacies; however, this should not be confused with pharmacies that are contracted with the AHCCCS FFS PBM or the AHCCCS Contractors’ PBMs. The first is how the pharmacy procures the drug and the latter is how payment is issued for the drug when it is dispensed to an AHCCCS member. Irrespective of any arrangement that FQHC’s and FQHC Look-Alikes have with a contracted pharmacy, the FQHC or FQHC Look-Alike must submit claims for drugs eligible for 340B pricing to the AHCCCS FFS PBM and/or AHCCCS Managed Care Contractors’ PBMs with the lesser of the actual acquisition cost of the drug or the 340B ceiling price. This is a similar model to that of other states. The submission of this amount also creates a fully transparent model whereas the replenishment model does not provide transparency.

evaluation or justification of the rule where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material. In this section, the agency has responded by stating, “The Administration has analyzed the data through the study and AHCCCS claims data at the NDC level for the 1st quarter of 2011; the results of this analysis demonstrated a net savings valued at approximately \$7.1M annually”. The methodology behind the above-mentioned data analysis exercise has not been clearly described in this or other sections of the preamble. Section 9 mentions that the ‘The AHCCCS Administration believes that the cost differential, when comparing 340B pricing to the PBM reimbursement rate paid to the 340B entity and its contracted pharmacy, can be saved and benefit the state’. As you are aware, 340B claims may not be submitted to manufacturers by Medicaid programs for rebates because the manufacturer has already extended a discount to the covered entity when the drug was initially purchased. It is unclear whether AHCCCS’ analysis accounted for the loss of revenue to the state from not collecting rebates as a result reimbursing the pharmacy using 340B drug pricing. Until this loss of revenue from rebates is factored in, the estimated \$7.1 million figure quoted is potentially overstated.

It is vital that the data and methodology employed in the analysis, and any supporting material be

AHCCCS calculated a potential savings of \$7.1 M for its expenditure for prescription drugs under the proposed reimbursement methodology based on prescriptions that were purchased through the 340B Pricing Program by FQHC’s and FQHC Look-Alikes. The analysis did not include prescriptions filled and dispensed to AHCCCS members by 340B entity contracted pharmacies. AHCCCS is not permitted to submit claims, for drugs purchased under the 340B Pricing Program, to manufacturers and subsequently collect rebates from them under the federal rebate program as this would be considered obtaining “duplicate discounts” (one for the 340B entity and the second for the state Medicaid agency). The proposed rule, revised through supplemental rulemaking, requires that FQHC and FQHC Look-Alike pharmacies identify all drugs dispensed which are eligible for 340B pricing upon submission to the AHCCCS FFS PBM and/or the AHCCCS Managed Care Contractors’ PBMs to ensure that duplicate discounts are prevented.

transparently available to all stakeholders.

3. Section 7 relies on the “Cost of Dispensing Study” as the basis for setting the \$8.75 dispense fee to entities and contract pharmacies. It is important to note however that the Grant Thornton study concluded that the median cost to fill a prescription is \$10.50 in 2007, nearly five years ago. AHCCCS indicated it used an adjustment factor based on geographic practice cost indices to determine the Arizona cost of dispensing. However, Section 7 does not provide the analysis or other supporting data related to that adjustment factor for the public to review. In the event that AHCCCS decides to elect to proceed with implementation of the proposed rule despite the concerns expressed, there are serious risks that contract pharmacies will be reimbursed by AHCCCS below the pharmacies’ true costs, creating further negative impacts to the pharmacies and the 340B program. One such impact may be the reduction in 340B contract pharmacies in Arizona thus limiting the availability of pharmacy care which the 340B program was intended to promote and broaden. Alternatively, contract pharmacies would look to the covered entity to make up for the short fall in reimbursement received from AHCCCS. If a contract pharmacy agreed to accept reimbursement rates below its cost on behalf of the covered entity, such arrangement could implicate the Federal Anti-Kickback Statute which prohibits one entity from

The Grant Thornton study is one among several information sources viewed by AHCCCS. Section 7 of the preamble has been revised to clarify this.

The COD cited by the commenter is identified in that study as the “average per prescription.” AHCCCS believes that, given the likelihood of outliers in the type of data studied, median is the better measure of central tendency.

In viewing the Grant Thornton study, as well as other studies presenting similar information, AHCCCS gave its attention to the median COD per prescription.

The AHCCCS FFS PBM and AHCCCS Managed Care Contractors’ PBMs provide statewide networks and access to care that meet Medicaid standards. The contracts between 340B entities and their contract pharmacies do not affect these statewide networks and members can obtain pharmaceutical services from an extensive network of pharmacies throughout the

providing another entity any remuneration in exchange for referrals of patients. Consequently, the reimbursement amounts that covered entities would have to pay contract pharmacies to make up for the shortfall in AHCCCS payments would reduce the resources available to that covered entity to provide greater access to healthcare as intended by the 340B program.

4. Pharmacy industry participants, including other State Medicaid Agencies, are using the NCPDP forum to develop a solution where Medicaid agencies will be able to meet the requirements to participate in the Federal Medicaid Drug Rebate Program, and comply with regulations prohibiting duplicate discounts. The approach outlined in the proposed rule is at odds with the solution being developed at NCPDP with broader stakeholder representation and input. This solution is expected to be ready for implementation during 2012 and is described in the 'Potential Solutions' section below.

Potential Solutions:

There are two mutually exclusive solutions available to allow State Medicaid agencies with the regulation to participate in the Federal Medicaid Drug Rebate Program, while preventing duplicate discounts as required under federal regulations for the 340B program.

state.
AHCCCS has not identified any implications with the Federal Anti-Kickback Statute and suggest you confer with your legal counsel.

1. Similar to the current practice of carving-out FFS Medicaid programs, covered entities and contract pharmacies are able to carve-out Medicaid MCO claims from the 340B-qualified claims set. Under this arrangement, Medicaid programs can safely collect rebates from manufacturers without risk of duplicate discounts, since the pharmacy's non-340B acquisition costs are always used to submit and reimburse claims.
2. Under the next HIPAA-approved version of the NCPDP Standard (Version D.0), solutions are being developed to eliminate risk of duplicate discounts that address both the prospective and the replenishment models in use in the 340B industry today. The timeline for implementation of these solutions is during 2012.
 - a. **Prospective Model Solution:** If a pharmacy knows at the time of claim submission that product obtained at 340B drug pricing will be dispensed, an identifier on the outbound claim will be set on the claim to identify it as 340B. The ingredient cost field is also modifiable to submit the 340B acquisition cost.
 - b. **Replenishment Model Solution:** Pharmacies will be able to retrospectively identify to the PBM/processor any claims where they received inventory replenishment at 340B pricing. The PBM/processor will exclude these prescriptions from the rebate processing with manufacturers.

AHCCCS will amend the proposed rule to specify that AHCCCS shall not reimburse 340B Contracted Pharmacies for 340B purchased drugs. However, contracted pharmacies that are in the AHCCCS FFS and Managed Care Contractors Pharmacy Networks may continue to submit claims to the AHCCCS FFS and Managed Care Contractors' PBMs for reimbursement of drugs that are not purchased through the 340B Pricing Program... Reimbursement to contracted pharmacies is limited to contracted pharmacies in the AHCCCS or Managed Care Contractor network for drugs not purchased under the 340B program. AHCCCS and Managed Care Contractors shall reimburse these drugs at the price and dispensing fee set forth in the contract.

Per the proposed rule, AHCCCS will communicate prescription claims submission requirements, including, but not limited to, the NCPDP claims submission fields for the "340B Claim Identifier" and the Actual Acquisition Cost/340B Ceiling Price to the AHCCCS FFS PBM and to AHCCCS Managed Care Contractors.

5. 10/21/2011 The proposed rule would require certain covered entities to bill
Maureen AHCCCS and its contractors at the 340B ceiling price plus a
Testoni, dispensing fee of \$8.75. As discussed below, the undersigned
Assistant organizations, which represent safety net providers that
General participate in the 340B program, have grave concerns about
Council, such a policy and believe that it is contrary to federal law. We
Safety Net recommend that AHCCCS instead consider a reimbursement
Hospitals for policy that may have greater savings potential wherein

Pharmaceutical Access AHCCCS and covered entities share the savings generated when drugs are purchased with the 340B discount.

A. The Proposed Rule Conflicts with the Federal Exemption of 340B Drugs from Managed Care Rebates

The preamble to the proposed rule states that AHCCCS is imposing this rule as a result of the Patient Protection and Affordable Care Act (PPACA), which required all state Medicaid programs, including AHCCCS, to participate in the federal drug rebate program. The preamble further states that 340B drugs are not eligible for rebates and that this prohibition is intended to protect manufacturers from paying two discounts on a drug – the 340B discount and the Medicaid rebate. Finally, the preamble explains that it is imposing this lower reimbursement rate in order to address the disparity between the actual acquisition cost of drugs subject to 340B pricing and the current reimbursement rate received from pharmacy benefit managers (PBMs).

Prior to PPACA, drugs furnished by Medicaid managed care plans were exempt from rebate requirements. PPACA extended Medicaid fee-for-service drug rebate requirements to Medicaid managed care. By imposing an obligation on states to collect rebates, PPACA created a new revenue stream for states.

Importantly, 340B drugs were specifically exempted from this requirement and the new revenue stream for states. The purpose of this exemption was not to protect managed care organizations from duplicate discounts, as there is already language in the

The provisions of sections 340B of the Public Health Service Act and Section 1927 of the Social Security Act regarding duplicate payments were not intended to protect 340B covered entities such as FQHC's and FQHC Look-Alikes. These laws were enacted to protect drug manufacturers from having to provide BOTH a discount to a 340B entity and a rebate to the State Medicaid agency for the same drug. Neither section 340B of the Public Health Service Act nor the Medicaid Act restricts the State Medicaid agency for establishing the reimbursement method established in this rule; in fact, HRSA directs entities to their respective state for guidance.

340B statute prohibiting covered entities from requesting payment under Medicaid for 340B drugs. Rather, the intent was to protect 340B covered entities and the vulnerable patients they serve by exempting the 340B program from the new revenue stream created for the states. In this way, Congress preserved the existing status quo. States were not receiving revenue from 340B managed care drugs prior to PPACA, and the exemption ensured that they would not receive any such revenue as a result of PPACA. AHCCCS's proposal to mandate billing to managed care organizations at the 340B ceiling price conflicts with the federal exemption for 340B from the Medicaid managed care rebate requirements, and is therefore pre-empted by PPACA.

This federal protection is consistent with Congressional intent with regard to the 340B program. Congress created the 340B program to enable safety-net providers to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services." This purpose cannot be achieved if 340B covered entities have to pass on all of the savings they receive from third parties. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give providers when it established the 340B program. As discussed in a recent report by the Government Accountability Office (GAO), 340B providers are using the additional revenue they receive to further the program's purpose, such as by maintaining services and lowering medication costs for patients. The GAO also reported that many covered entities do not generate enough revenue from the 340B

program to offset drug related costs. AHCCCS's proposal undermines the very nature of the 340B program and will result in fewer services and other assistance for vulnerable patient populations.

B. The Proposed Rule Interferes with Federal Requirements Governing Medicaid Managed Care Plans

Imposing fee schedules that managed care organizations must follow may impermissibly interfere with federal statutory requirements. The provisions in the Medicaid statute that govern use of managed care arrangements specifically state that payment to managed care entities is to be made on a prepaid capitation basis. The statute is clear that this involves the allocation of risk. Under this model, states pay a prospective amount per recipient to the managed care organization in return for the organization providing all covered services to Medicaid recipients. In order for the managed care organization to furnish the care within the payment amount received, the organization must *manage* the recipients' care, which involves negotiating payment rates with providers, utilization review, etc. By imposing reimbursement requirements on managed care companies, AHCCCS is interfering with the allocation of risk and the organization's obligation to manage enrollees' care, which conflicts with the federal requirements cited above.

C. The Proposed Rule Violates Federal Confidentiality Requirements, HRSA Guidance, and Requests Information that 340B Entities Currently Do Not

The Managed Care provisions of the Medicaid Act do not prohibit the State Medicaid agency from establishing reimbursement methodologies for particular items or services that are binding on MCOs. Capitation rates take this methodology into consideration.

Neither Section 340B of the Public Health Service Act nor Section 1927 of the Social Security Act prohibits an FQHC, FQHC Look-Alike, or their contracted pharmacies from

Possess

providing this information to a State Medicaid agency.

The proposed rule also contains a provision that requires 340B entities to “provide the 340B pricing file to the AHCCCS Administration upon request.” This requirement violates federal confidentiality requirements, guidance issued by the Health Resources and Services Administration (“HRSA”), and copyright laws. Moreover, covered entities do not have access to any ceiling prices that they can be assured are accurate and are prohibited from sharing estimated ceiling prices they receive from wholesalers.

The 340B ceiling price is defined in Section 340B of the Public Health Services statute as “the maximum price that covered entities may permissibly be required to pay” for a 340B drug. The ceiling price is calculated based on a drug’s average manufacturer price and “best price,” both of which are defined in section 1927 of the Social Security Act. The Medicaid statute, the 340B pharmaceutical pricing agreement (“PPA”), and HRSA guidance all provide, with some variation, that the information disclosed by the manufacturer is confidential and prohibits disclosure of this information. The Medicaid drug rebate statute, at Section 1927(b)(3)(D) of the Social Security Act, specifies that drug pricing information “shall not be disclosed by the [Government] . . . in a form which discloses the identity of a specific manufacturer or wholesaler, [or] the prices charged for drugs” except as necessary to carry out the provisions of the Act or for certain other limited purposes, including the Medicaid rebate program. HRSA has taken the

position that 340B ceiling prices could be considered this type of “form” that would reveal manufacturers’ prices. In line with this reasoning, HRSA has interpreted this provision to mean that covered entities may not disclose 340B ceiling prices.

Pharmaceutical manufacturers rely on this guidance and are quick to take action when they believe their calculated 340B ceiling prices have been improperly disclosed.

We are aware that, pursuant to PPACA, the Department of Health and Human Services (HHS) is required to make 340B ceiling prices available to covered entities on a password-protected website. Nothing in PPACA, however, authorizes a covered entity to disclose its 340B prices to a payer. Likewise, there is nothing in the Medicaid statute, PPA, or HRSA guidance that establishes an exception to 340B confidentiality standards when a covered entity bills its 340B drugs. Therefore, mandating disclosure of ceiling prices violates federal law.

In addition, covered entities currently do not have access to this information. The pricing information from manufacturers that is necessary to calculate the ceiling price is not publicly available. It is for this reason that PPACA included language requiring that HHS make ceiling prices available to covered entities, as there is currently no way for them to determine whether they are being charged the correct 340B ceiling price. Covered entities must rely on 340B price lists that are published by wholesalers, though there is no way for them to evaluate whether the price on the list truly represents the 340B ceiling price. Such lists, however, are not available to the public and wholesalers and

manufacturers have not authorized covered entities to disclose this information. Manufacturers consider such information to be proprietary and object to the sharing of such information.

See above response for item 5(A).

D. AHCCCS Should Evaluate the Potential Savings to be Gained by Sharing a Higher Percentage of the 340B Discount with Covered Entities

The proposed rule sets a dispensing fee for 340B drugs of \$8.75. We have been told that this rate is well below the cost of dispensing for the vast majority of covered entities affected by the proposed rule. As mentioned above, the GAO recently found that covered entities use the savings from the 340B discount to maintain services and lower medication costs for patients, though for many, savings from the 340B program is insufficient to cover drug related costs. Lowering reimbursement to cost and establishing a below-cost dispensing fee could have a catastrophic impact on these covered entities and their patients. It is also likely to lead to less savings for AHCCCS than could be achieved with a dispensing fee that was closer to covered entities' true costs.

The Office of the Inspector General (OIG) recently issued a report evaluating State Medicaid policies related to the 340B-purchased drugs. The OIG concluded that many states misunderstand federal policy regarding 340B billing and that states could save money through shared savings arrangements with covered entities even if the state paid such entities higher dispensing fees. By requiring covered entities to bill their actual

acquisition cost (AAC), Medicaid agencies are leading nearly 60 percent of covered entities to carve-out their Medicaid drugs from 340B purchases. When a covered entity carves-out, it does not have access to the 340B discount and Medicaid pays its standard reimbursement rate for the drugs and the state receives only the Medicaid rebate as its discount. Typically, the 340B price is significantly lower than the standard Medicaid rate after rebate, therefore, as a result of the AAC billing policies, States are foregoing higher discounts on drugs than they currently receive through the rebate program. Covered entities carve-out in these situations because the dispensing fee associated with the AAC payment rate is much lower than the covered entities' actual cost to dispense the drug, resulting in a significant loss when dispensing 340B drugs.

Recognizing the potential for higher drug savings, some states have developed reimbursement policies that set payment levels to encourage covered entities to use 340B drugs for their Medicaid patients. In this way, states and providers share the spread between the 340B discount and the standard Medicaid reimbursement rate. These "shared savings" policies result in a win-win for both state Medicaid programs and covered entities.

For example, Massachusetts took steps in 2007 to increase its payment for 340B drugs with the goal of encouraging covered entities to carve-in to Medicaid. By offering an enhanced dispensing fee for 340B retail drugs of \$10.00, Massachusetts Medicaid dramatically increased the number of providers carving in their 340B drugs. When Massachusetts began

looking into this issue in 2002, only three covered entities carved-in to Medicaid. By 2010, the carve-in rate for DSH was over 75%, representing 68 registered sites. As a result, Massachusetts netted \$6.5 million in additional revenue in 2010 alone. Importantly, Massachusetts used its shared savings arrangement to improve access to lifesaving medications for the state's low-income population.

AHCCCS has the opportunity to establish a win-win situation with 340B entities in Arizona. Failure to do so is likely to result in some covered entities having to close their doors and other covered entities opting to carve-out their 340B drugs from Medicaid. Both situations result in lower savings for AHCCCS and potentially irreversible harm to the patients served by these covered entities. We strongly encourage AHCCCS to revisit the amount of the dispensing fee and to set the rate at a level that more closely reflects the true dispensing costs of the covered entities affected by this proposed rule.

6. John Pacey
Regional
Pharmacy
By the time the proposed rule is finalized in November, the Medicaid contractors will have less than 60 days to work with their Pharmacy Benefit Managers (PBM's) to plan, build, and

Director,
United Health
Care and State
APIPA

test the claims processing functionality of this new benefit.
Also, new contract addendums with the FQHC network also
need to be distributed, signed and returned by the FQHC
pharmacies.

PBM's are extremely busy in the October, November, December
quarter, building and testing all new benefits effective 1/1/12.
This short time frame would place an unnecessary burden not
only on the PBM, but on the contractors pharmacy departments
as well. This 340-B benefit is an entirely new program that will
require AHCCCS supplied pricing files, FQHC pharmacy
information, and a written process on exactly how the program
will operate, process claims, and submit encounter data to
AHCCCS correctly the first time. Any processing or pricing
glitches in the beginning could doom this project from the start
with the FQHC pharmacy network.

There are many moving parts, and different scenarios, that will
require at least 90 days to build, test, implement and notify
providers in advance of this major process change in contractor
pharmacy programs.

With the above, I ask that AHCCCS reconsider the start date of
this program and allow at least 90-120 days lead time for all
contractors to plan, build and implement the 340-B pharmacy
program to ensure it begins operating correctly from day one,
without any issues caused by contractors rushing to complete
the implementation by the proposed starting date.

AHCCCS recognizes that contractors and subcontractors may
require a minimum of 30 days to facilitate and implement the rule
requirements and will ensure timely notification is provided.

7. John Swagert, We believe the proposed changes in AHCCCS reimbursement

See above response for item 1.

CEO
Mountain Park
HC

to 340B FQHC pharmacies will do more harm than good. By providing a dispensing fee that is below the actual cost of dispensing medication, AHCCCS will be forcing pharmacies like ours to shift pharmacy costs to uninsured patients in order to maintain financially viable Pharmacy services.

It is of course true that AHCCCS is not responsible for the cost of care for the uninsured. But we know that our uninsured patients cycle on and off AHCCCS, just as they cycle on and off commercial insurance—as their individual economic circumstances change, as jobs are gained or lost, or as employers stop offering coverage. Uninsured patients with chronic conditions requiring long-term medications who can't afford to fill their prescriptions will be sicker, and costlier to take care of, should economic circumstances land them on the AHCCCS roles.

We join the Arizona Association of Community Health Centers in asking that AHCCCS reconsider the proposed dispensing fee of \$8.75. We further ask that AHCCCS use the data from The Grant Thornton National Cost of Dispensing (COD) Study Final Report January 26, 2007, cited by AHCCCS as a credible source, as the basis of a dispensing fee that could be expected to cover the actual cost. That study found a cost of over \$12 in 2006, which would be between \$14 and \$15 after adjustment for inflation.

8. 10/22/2011
Mary
- Our primary concerns are loss of revenue for both the in-house pharmacy and our contracted pharmacies, deterioration in
- See above response for item 1.

Brubaker, patient outcomes, and possible elimination of services within
Director of our clinics.
Pharmacy,
North Country HC The proposed reimbursement model of 340b acquisition cost
plus \$8.75 dispensing fee will result in a 26% decrease in
revenue from the AHCCCS managed care plans. In order to
maintain the same amount of revenue paid by AHCCCS to
North Country in 2010, the dispensing fee needs to be in the
range of \$15.50 to \$16.00 per prescription. At the initial
meeting with the medical and pharmacy director of AHCCCS,
they stated it was their intent to make sure the CHC pharmacies
remained “whole”. Within the North Country service area are
several clinics in communities without retail pharmacy services.
Currently the North Country pharmacy provides through a
variety of options, medication deliveries to the local clinic for
distribution to those patients. With the change in
reimbursement, these patients may need to find other means for
securing their medications or simply go without.

Medication adherence remains a major player in the overall
healthcare costs to our state. Many factors are involved in why
patients do not take their medications. Since cost is generally
not one of the factors with AHCCCS coverage, consideration
needs to be given to the patient’s understanding of the value of
the medications in their care, adverse reactions, and simply
transportation barriers. The focus of community health center
pharmacies is to provide care for uninsured and underserved,
and to minimize health care disparities. The loss in revenue will
likely affect our services to the patients most at risk. (Lars
Osterberg, M.D., and Terrence Blaschke, M.D. *N Engl J Med*

2005; 353:487-497; Adherence to Long-Term Therapies, Evidence for Action, WHO 2003.)

If the pharmacy is not able to at least break even on AHCCCS prescriptions, then the center will need to reevaluate all services provided by the clinic. While the proposed change in the reimbursement model may be a short term fix, the down stream effect will likely be an increase in patient medical costs. The utilization of the emergency room increases, absenteeism increases and productivity decreases. The question to be answered is if the increase in pharmaceutical rebates will offset the increase in medical care costs. (Asheville Project, Barry A. Bunting, Benjamin H. Smith, and Susan E. Sutherland *J Am Pharm Assoc.* 2008; 48:23–31).

We encourage AHCCCS to reconsider their proposed reimbursement model, and either return to the current contract pricing, or to increase the dispensing fee to more closely reflect the pharmacy's cost. It is the intent of all of us to provide the best care for these vulnerable patients.

9. 10/23/2011
Kathy Byrne,
CEO
El Rio Comm
HC
- The El Rio Community Health Center wishes to highlight our concerns with the proposed regulations relating to the 340b program and its impact on organizations like our own. While we were heartened by the early discussion with representatives of AHCCCS regarding supplementing the acquisition cost payment methodology with an enhanced dispensing fee the fee proposed of \$8.75 falls short of our cost of operating pharmacy services. The introduction to the proposed regulations draw attention to

See above response for item 1.

the Grant Thornton National Cost Study which is based on 2006 costs and shows an average dispensing cost of \$12.31 for Medicaid. If this analysis was framed in current dollars using the physician CPI the cost of dispensing would be \$14.82. Given the study that AHCCCS highlighted we are at a loss to understand why the fee of \$8.75 was chosen.

For the El Rio Community Health Center the implementation of this change in our method of reimbursement means a loss of over \$4.00 per prescription- a loss of over \$700,000 based on our current volume. We are even more concerned with the very recent news that Walgreens will no longer participate in the pharmacy network of some of the health plans serving Pima County. It is likely we will see growth in the number of our AHCCCS patients using our pharmacies and ever more significant losses.

We would encourage AHCCCS to look more fully at the impact of the proposed rule and the possible unintended consequences associated with the proposed change including health centers having to reduce access to pharmacy services. We believe that rather than restricting access to 340b program benefits the State should be encouraging greater use of this great program.

We would also like to support the analysis that has been presented and submitted by the Arizona Association of Community Health Centers.