Iowa Department of Human Services



Recommendation for Pharmacy Reimbursement Methodology Change in Response to House File 649

December 2011

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Executive Summary

Overview

Division IV, Section 10(24) of House File 649 directs the Department to consult with the Iowa Pharmacy Association and other appropriate entities to develop recommendations for replacement of the current methodology used for pharmacy reimbursement in the Iowa Medicaid program and to submit those recommendations to the Legislative Services Agency by December 15, 2011. This document constitutes the Department's report issued in compliance with the legislative direction.

The Iowa Medicaid Enterprise ("IME") hosted a stakeholder meeting in October 2011 with the purpose of soliciting feedback and ideas from the stakeholders. The stakeholders invited to the October meeting included the Iowa Pharmacy Association (IPA), national independent and chain drug store associations, pharmaceutical manufacturers and their trade organization, and all enrolled pharmacy providers. In addition, the draft report was released and a follow up meeting was held on December 6, 2011, to receive comments on the draft report.

Iowa Medicaid's current reimbursement methodology incorporates the Average Wholesale Price ("AWP") benchmark for brand and generic drugs. Reimbursement with this benchmark is the AWP minus a percentage. However, evidence consistently finds that the AWP benchmark is wildly inaccurate and grossly overstated in many cases, earning the reputation of representing "Ain't What's Paid." Federal law obligates Iowa Medicaid to reimburse pharmacies based on "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers."¹ In addition, federal regulations require Medicaid programs to apply "a reasonable dispensing fee established by the agency."²

To fulfill the obligation to provide the best estimate of drug prices paid by providers, AWP should be replaced as one of the benchmarks upon which reimbursement is based. The replacement option should be reflective of costs paid by pharmacies for drugs. It should be transparent to reduce susceptibility to the manipulation that affected the AWP. The benchmark should also be updated in a timely manner and accessible to the state.

While an extensive list and discussion of potential replacement benchmarks is found in this paper, the two most viable options are replacement of AWP reimbursement with Average Acquisition Cost ("AAC") or Wholesale Acquisition Cost ("WAC").

Average Acquisition Cost ("AAC")

AAC represents the average amount paid by pharmacies to suppliers (e.g., wholesalers, manufacturers) for brand and generic drugs. Medicaid agencies calculate AACs by

¹ 42 C.F.R. § 447.502. ² 42 C.F.R. § 447.331. obtaining drug acquisition invoices from participating Medicaid pharmacies. The Iowa Medicaid program utilizes this model in establishing the State Maximum Allowable Cost ("SMAC") program, which means that Iowa pharmacy providers are already familiar with the procedures and processes for submitting requested information. Such invoice surveys require minimal administrative effort and can be completed by non-pharmacist personnel. Because AAC is based on the actual prices that pharmacies pay for drugs, the use of AAC in the Iowa Medicaid pharmaceutical reimbursement methodology best accomplishes the obligations imposed on the state by federal law. Three other Medicaid programs - Alabama, Oregon, and Idaho - currently use AAC-based reimbursement for brand and generic drugs.

- Reflective of drug costs: Yes. AAC is based on costs reported by pharmacies.
- Transparency: <u>Yes</u>. The source of AAC data lends to the benchmark's transparency.
- Resistant to manipulation: <u>Yes</u>. AAC uses documented prices reflecting actual transactions, and therefore, is not susceptible to manipulation.
- Timeliness: Yes. AAC rates can be updated as frequently as daily.
- Able to address provider appeals: <u>Yes</u>. AAC rates can be adjusted when any inequities are identified in the system, which provides the Medicaid program the ability to address providers' concerns on appeals.
- Comprehensive of all NDCs: <u>No</u>. Aside from AWP, no other benchmark is comprehensive of all NDCs.

Wholesale Acquisition Cost ("WAC")

WAC is purported to be the manufacturers' catalog or list price for drugs to wholesalers, which eventually go on to sell the drugs to pharmacies. When payors use WAC as a pricing benchmark, such payors normally increase WAC by some percentage to establish the estimated price paid by the pharmacy. Manufacturers determine the WACs for their own pharmaceuticals. Both the IPA and the National Association of Chain Drug Stores ("NACDS") requested that the Department consider a WAC-based reimbursement for brand drugs.

- Reflective of drug costs: <u>No</u>. Manufacturers do not use a consistent, defined method to calculate the WAC.
- Transparency: <u>No</u>. It is not clear how manufacturers determine WAC.
- Resistant to manipulation: <u>No</u>. Because WAC calculation remains undefined, it is susceptible to manipulation that also affected AWP.
- Timeliness: <u>Yes</u>. Updated publishers' files that contain WAC may be available as frequently as daily.
- Able to address provider appeals: <u>No</u>. Because WAC rates are established by the manufacturer, they cannot be updated by Medicaid.
- Comprehensive of all NDCs: <u>No</u>. Aside from AWP, no other benchmark is comprehensive of all NDCs.

Reimbursement

There are two components to pharmacy reimbursement for a drug, ingredient cost and a dispensing fee.

Ingredient Cost

The ingredient cost of the drug is currently reimbursed by Medicaid on an AWP-based methodology. The IPA and the NACDS requested consideration of the use of the WAC for calculating reimbursement rates that are cost neutral to the current AWP-based rates. However, there are issues with the use of the WAC benchmark in the Iowa Medicaid reimbursement methodology. The Office of the Inspector General ("OIG") has consistently found that AWP-based reimbursement has caused Medicaid to pay too much for drugs, so maintaining reimbursement at a cost neutral level to AWP-based reimbursement would not address overpayment for drugs.³ The methods used to establish the WAC benchmark lack transparency and the process leaves the benchmark susceptible to the same manipulation by manufacturers that plagued AWP. Shifting from an AWP-based methodology to a WAC-based methodology does little than put a new coat on an old problem.

Dispensing Fee

In addition to the drug ingredient cost, pharmacy reimbursement for drug claims involves the payment of a dispensing fee. A dispensing fee compensates the pharmacy for transferring the drug from the pharmacy to the patient. The Centers for Medicare and Medicaid Services ("CMS") has directed states to evaluate their dispensing fees when considering a change in the ingredient cost reimbursement. Iowa's current Medicaid dispensing fee is \$6.20. Some cost of dispensing studies have shown that pharmacies spend an estimated \$10 to \$11 to dispense a prescription in addition to the ingredient cost of the drug product.⁴ Increasing the dispensing fee without providing a true estimated acquisition cost of the pharmaceuticals would not comport with federal Medicaid obligations. Therefore, moving from an AWP reimbursement methodology to a "cost neutral" WAC approach would be inappropriate. Likewise, if the state moved to an AAC model, we anticipate that the dispensing fee would need to approximate the cost of dispensing, as verified by a cost of dispensing study.

Cost Consideration

For AAC reimbursement, there will be an additional contract cost for the added scope of services of collecting pharmacy invoices and calculating AAC, though this cost would take into account that established operations already exist. Shifting from AWP-based rates to AAC-based rates has resulted in ingredient cost savings far above the AAC program operations costs in other states that have implemented this reimbursement approach. The level of savings is determined by program policy and baseline reimbursement. The Department anticipates that the dispensing fee would need to be

³ "Replacing Average Wholesale Price: Medicaid Drug Payment Policy." Office of Inspector General. July 2011.

⁴ "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies." Grant Thornton, Jan 2007; "Cost of Dispensing Prescription Drugs in Alabama. Final Report." Health Information Designs, Jan 6, 2010.

increased from the current \$6.20 to an amount that approximates the result of a cost of dispensing study. If the dispensing fee is increased, savings from the ingredient cost portion of reimbursement would help offset the additional dispensing fee cost. Although WAC is available to the state at no additional cost due to its availability on currently used data files, there are associated costs to consider, such as the process utilized to establish reimbursement rates for drugs with no reported WAC. The IPA and the NACDS suggested a WAC-based reimbursement that would maintain the current level of reimbursement that is provided with AWP-based reimbursement rates, while maintaining the current dispensing fee of \$6.20. However maintaining the same level of inflated AWP reimbursement while maintaining the current dispensing fee, does not fulfill the federal obligation to base reimbursement on estimated acquisition cost and a reasonable dispensing fee. Additionally, for the WAC plus reimbursement to be cost neutral, the WAC reimbursement would have to be set below the current AWP-based reimbursement levels to offset any potential increase to the dispensing fee.

Both the AAC and WAC reimbursement approaches would presumably be associated with new program costs to conduct a pharmacy dispensing fee study, a potential increase in the dispensing fee, and system programming changes.

Recommendation

With consideration of the options available to the state at the time of this writing and the suggestions of the stakeholders, the Department recommends <u>replacing the current</u> <u>AWP-based reimbursement methodology with an AAC-based reimbursement methodology</u> that is budget-neutral to the current overall reimbursement.

With the recommended change in reimbursement, the Department also recommends performing a cost of dispensing study to evaluate the reasonableness of the current lowa dispensing fee. Any potential change to the dispensing fee should be implemented concurrently with the change to the ingredient cost reimbursement methodology.

The recommendation would result in AAC-based methodology with a dispensing fee supported by the cost of dispensing study, which has not yet been completed. A dispensing fee in the range of \$11.10 has been projected, through modeled fiscal estimates, to result in an estimated fiscal impact of a net savings of approximately \$100,000 total annually. (See Table 2 of the appendix for fiscal estimate detail). Any change to the reimbursement methodology and dispensing fee is subject to CMS approval.

Through this recommendation to use AAC-based reimbursement, the Department seeks to shift pharmacy reimbursement to a transparent methodology that provides the best estimate of drug acquisition prices paid by providers. The use of the AAC for determining reimbursement rates meets this goal. Therefore, the Department proposes to replace the AWP-based reimbursement methodology with an AAC-based reimbursement methodology. The strengths of this approach over WAC or other benchmarks include transparency of the rate-setting process, freedom from rates manipulated by manufacturers, reliance on actual drug costs based on invoices, and timeliness of the rates established. Maintaining the current overall reimbursement

minimizes the impact of this change to the overall provider community and on patient access to drugs.

Iowa Medicaid Enterprise

House File 649 Required Report Recommendation for Pharmacy Reimbursement Methodology Change

I. Introduction

Division IV, Section 10(24) of House File 649 directs the Department to consult with the Iowa Pharmacy Association and other appropriate entities to develop recommendations for replacement of the current methodology used for pharmacy reimbursement in the Iowa Medicaid program and to submit those recommendations to the Legislative Services Agency by December 15, 2011. This document constitutes the Department's report issued in compliance with the legislative direction.

II. Background & Summary

Medicaid programs are in many respects like large health insurance companies in the sense that the programs pay reasonable and appropriate claims submitted by providers but do not directly buy those goods and services on the open market. When reimbursing pharmacies for pharmaceuticals provided to Iowa Medicaid enrollees, federal law obligates lowa Medicaid to pay a reasonable value for the drug cost as well as a reasonable fee for the pharmacists' time and effort in filling a prescription. See 42 U.S.C. §§ 1396a(a)(23), (32). Federal Medicaid regulations further define this "reasonable value" obligation by mandating that Medicaid programs reimburse pharmacies based on an Estimated Acquisition Cost ("EAC") of the pharmaceuticals. 42 C.F.R. § 447.301. The regulations go on to define EAC as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." Id. In addition, federal regulations require Medicaid programs to apply "a reasonable dispensing fee established by the agency." 42 C.F.R. § 447.332.

To aid payors such as Medicaid in reimbursing pharmacies for pharmaceuticals, some companies began publishing pricing benchmarks that could be used as a basis for arriving at a reasonable EAC.

A. Pricing Benchmarks

Any discussion of the use of appropriate benchmarks must of necessity begin with a description of the published benchmarks as well as a review of other pricing restrictions imposed under federal law. The following is a brief description of the major benchmarks currently used in pharmaceutical pricing.

i. Average Wholesale Price ("AWP")

Nearly every state Medicaid program has historically utilized a benchmark known as the "average wholesale price" or "AWP" in its pharmacy reimbursement methodology, as

has been the case "for most pharmaceutical sales in the United States." Reimbursement with this benchmark is the AWP minus a percentage. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 67 (D. Mass. 2005); Department of Health and Human Services, Office of Inspector General: *Replacing Average Wholesale Price: Medicaid Drug Payment Policy* at p. i (July 2011) (noting that as of the first quarter of 2011, 45 states used AWP in their Medicaid reimbursement methodology).

First DataBank was one of the publishers of the AWP benchmark. As late as 2000, First DataBank reported that its AWP benchmark represented "the average of the prices charged by the national drug wholesalers for a given product." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 68 (D. Mass. 2005). However, evidence began to mount that the AWP benchmark was wildly inaccurate and grossly overstated in many cases. In January 2007, Senator Chuck Grassley mockingly referred to the AWP benchmark as "like the sticker price for a car," and noted that the joke in the industry was that "AWP actually stood for 'Ain't What's Paid." Floor Statement of U.S. Senator Chuck Grassley, of Iowa – "Medicare Part D Is Working – If It Ain't Broke, Don't Fix It", (available at http://finance.senate.gov/newsroom/ranking/ download/?id=a336866a-4d95-4be8-b47b-a718b64c669d).

Following the resolution of a national class action brought against First DataBank related to published AWP prices, the publisher decided to discontinue publishing the AWP benchmark in September 2011. *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 602 F.Supp.2d 277, 283 (D.Mass. 2009); Department of Health and Human Services, Office of Inspector General: *Replacing Average Wholesale Price: Medicaid Drug Payment Policy* at p. i (July 2011). The other AWP benchmark publisher, Medi-Span, also considered discontinuing publication of the AWP but has since decided to continue publishing the benchmark at this time. Iowa Medicaid currently continues to rely on the Medi-Span AWP for calculation of the EAC.

ii. Average Manufacturer Price (" AMP")

For purposes of calculating manufacturer rebates owed to the federal and state governments, Congress mandated that all pharmaceutical manufacturers who participate in federally-funded health care programs must submit drug pricing information to the federal government. 42 U.S.C. § 1396r-8 (2011). One price point that manufacturers must submit is known as "average manufacturer price" or "AMP," which the statute defines as "the average price paid to the manufacturer for the drug in the United States" by either wholesalers for drugs distributed to retail community pharmacies, or retail community pharmacies that purchase drugs directly from the manufacturer. *Id.* § 1396r-8(k)(1). The pricing benchmark seeks to establish the "average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts." Department of HHS, Office of Inspector General, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices* p. i (2005). The AMP pricing information is based on actual sales transactions. *Id.* Historically, AMPs are reported to the federal government for all Medicaid-covered

drugs as a requirement of the Medicaid drug rebate program; most Medicaid programs do not receive the AMPs.⁵ In accordance with section 1927(b)(3) of the Social Security Act (the "Act"), the Centers for Medicare and Medicaid Services ("CMS") began providing states in August 2011 with values concerning AMP and AMP Units in a file within the Drug Data Reporting for Medicaid System ("DDR"). The AMP and AMP Units are calculated on a monthly basis by drug manufacturers that participate in the Medicaid drug rebate program and are reported to CMS in accordance with the Act's requirements. Drug manufacturers certify the accuracy of AMPs in accordance with Federal regulations at 42 CFR 447.510(e). However, the AMPs have not been verified or audited by CMS. It is not clear whether there are limitations to the use of this data, such as confined only to use within the Drug Rebate program.

iii. Federal Upper Limit ("FUL")

To address overpayment of drugs by various state EAC formulas, CMS instituted the Federal Upper Limit ("FUL") program, in which CMS assigns the maximum allowable costs or "MAC" for "multiple source" drugs (generally, drugs with generic equivalents, both brand and the generic being subject to the FUL). See http://www.cms.gov/ reimbursement/05 federalupperlimits.asp. The federal government's approach to establish FULs has changed over the years. Most recently, a provision of the Affordable Care Act mandated that CMS calculate FULs as no less than 175 percent of the weighted average of the most recent reported AMP. This new FUL calculation methodology has been the subject of intense scrutiny by pharmacy associations that have asserted the calculations place reimbursement below actual acquisition costs on more than half of the prescriptions filled by the pharmacies. Michael Johnsen, NCPA: Latest FUL list from CMS 'disaster making' а in the (available at www.drugstorenews.com/article/ncpa-latest-ful-list-cms-disaster-making). States can pay more than the FUL for a multiple source drug. However, under federal law, aggregate payments for all multiple source drugs may not exceed the aggregate FULs. This allows the Medicaid program to pay more than the FUL for some drugs as long as total amount reimbursed remains below the aggregate FUL for all drugs subject to federal limits.

iv. Wholesale Acquisition Cost ("WAC")

One of the other benchmarks often used in the industry is known as "Wholesale Acquisition Cost" or "WAC," which is "understood to be the price a pharmaceutical firm typically sells a drug to wholesalers." Reimbursement with this benchmark is the WAC plus a percentage. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 67 (D. Mass. 2005). For brand-name, self-administered drugs, the relationship between WAC pricing and AWP pricing has shown that the AWP price is 20% to 25% above the WAC price. For generic drugs, the relationship is less established, "with AWPs sometimes reaching 50% to 100% above WAC." *Id.* Historically, payors such as Medicaid programs have reimbursed at some discount off of

⁵ "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices." Office of Inspector General. June 2005.

the published AWP price.⁶ Additional discounts available to the provider/pharmacy from the wholesaler are not taken into consideration with the WAC or AWP benchmarks.⁷

Even though WAC pricing benchmarks are felt to be somewhat more reliable than the AWP benchmark, numerous state and federal court actions have asserted that various manufacturers have been involved in or acquiesced to the reporting of fraudulent WAC prices for their pharmaceuticals. See, e.g., U.S. ex rel. Ven-A-Care v. Activis Mid Atlantic, LLC, 659 F.Supp.2d 262, 271-72 (D. Mass. 2009); Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc., 2001 WL 3946941 at *10-*11 (Pa. Commonwealth 2011) (noting some manufacturers report WAC to publishing compendia but sell drugs to wholesalers at prices below WAC); Department of Health and Human Services, Office of Inspector General: Replacing Average Wholesale Price: Medicaid Drug Payment Policy at p. iii (July 2011) (noting that WAC, like AWP, is "a manufacturer reported benchmark that, like AWP, is not based on actual sales transactions.").

v. State Maximum Allowable Cost ("SMAC")

In addition to the other pricing constraints placed on pharmaceutical reimbursement, some states, including Iowa, have also implemented an average acquisition cost-based State Maximum Allowable Cost ("SMAC") programs to further control the reimbursement for generic drugs. The SMAC process involves collection of pharmacy invoices from a sample of Iowa pharmacies, which are utilized in setting the SMAC rates. In Iowa, the SMAC rate for generic drugs is set at the average price paid for the generic drug adjusted by a multiplier of 1.2 to account for variations in purchasing power of the pharmacies.

B. Iowa Medicaid Current Reimbursement Methodology

lowa Medicaid's current reimbursement methodology incorporates the AWP benchmark as follows:

- Pharmacies are reimbursed for covered generic prescription drugs based on the lowest of:
 - Estimated Acquisition Cost ("EAC"), defined as:
 - for nonspecialty generic prescription drugs AWP minus 12%, plus a professional dispensing fee;
 - for specialty generic prescription drugs AWP minus 17%, plus a professional dispensing fee;
 - Maximum Allowable Cost ("MAC"), defined as the upper limit for multiple source drugs established in accordance with 42 C.F.R. § 447.514, plus a professional dispensing fee. This is often referred to as the Federal Upper Limit or "FUL";

⁶ "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price." Office of Inspector General. June 2005.

⁷ Ibid.

- State Maximum Allowable Cost ("SMAC"), defined as the average wholesale acquisition cost for a generic drug (the average price pharmacies pay to obtain the generic drug as evidenced by purchase records) adjusted by a multiplier of 1.2, plus a professional dispensing fee;
- the "submitted charge, representing the provider's usual and customary charge for the drug."
- Brand-name prescription drug reimbursement is based on the lowest of:
 - Estimated Acquisition Cost ("EAC"), defined as:
 - for non-specialty brand prescription drugs AWP minus 12%, plus a professional dispensing fee;
 - for specialty brand prescription drugs AWP minus 17%, plus a professional dispensing fee;
 - the "submitted charge, representing the provider's usual and customary charge for the drug."
- Nonprescription (over-the-counter) drug reimbursement is based on the lowest of:
 - a maximum allowable cost set at the median of the AWP of all chemically equivalent products available;
 - the "submitted charge, representing the provider's usual and customary charge for the drug."

441 Iowa Admin. Code § 79.1(8)(a)-(b). Because the Iowa reimbursement methodology is the lowest of EAC, FUL, SMAC or usual and customary, the majority of generic drugs are reimbursed using the FUL or SMAC rates. Because Iowa SMAC rates are based on AAC, they are reflective of the providers' actual cost of generic drugs.

C. Dispensing Fees

As noted, in addition to the drug ingredient cost, pharmacy reimbursement for drug claims involves the payment of a reasonable dispensing fee. A dispensing fee compensates the pharmacy for transferring the drug from the pharmacy to the patient. CMS has indicated the necessity for states to evaluate their dispensing fees when considering any change in the ingredient cost reimbursement. Some cost of dispensing studies have shown that pharmacies spend an estimated \$10 to \$11 to dispense a prescription in addition to the cost of the drug product.⁸ These costs include pharmacy staff salaries, overhead costs, insurance, and fees among other expenses. Iowa Medicaid's current dispensing fee is \$6.20. The Medicaid dispensing fees for states contiguous to Iowa range from \$3.27 to \$5.00.⁹ However, when reviewing the dispensing fee it is important to take into account both components of pharmacy reimbursement for a drug, the ingredient cost methodology and the dispensing fee.

⁸ "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies." Grant Thornton, Jan 2007; "Cost of Dispensing Prescription Drugs in Alabama. Final Report." Health Information Designs, Jan 6, 2010.

⁹ Centers for Medicare and Medicaid Services. Medicaid Prescription Reimbursement Information by State-Quarter Ending September 2011.

http://www.cms.gov/Reimbursement/Downloads/3Q2011ReimbursementChart.pdf

Pharmacy brand drug reimbursement methodology, as confirmed by state Medicaid Pharmacy Directors at the time of this writing, is WAC plus 6% for ingredient cost plus a dispensing fee of \$3.25 to \$5.00 in Nebraska; AWP minus 15% for ingredient cost plus a dispensing fee of \$4.30 in South Dakota and WAC plus 2% for ingredient cost plus a dispensing fee of \$3.65 in Minnesota.

D. CMS Direction Regarding Pharmacy Reimbursement

The CMS has verbally provided some instruction with regards to state Medicaid agency plans to address pharmacy reimbursement shifts away from AWP.¹⁰ The CMS has suggested that states should seek to reimburse drug ingredients at a level more comparable to the actual product cost. In most cases, this will result in a decrease in the reimbursement for drug ingredients. At the same time, the CMS has directed states to conduct pharmacy "cost to dispense" studies and adjust state reimbursement of dispensing fees to a level supported by the study to provide pharmacies a dispensing fee that acknowledges their observed cost to dispense. Both parts of the reimbursement equation must be addressed for the CMS to consider approval of State Plan Amendments that ultimately change the reimbursement for drug ingredients.

E. CMS National Benchmark

In July 2011, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued a report entitled "Replacing Average Wholesale Price: Medicaid Drug Payment Policy." In that report, the OIG recommended that CMS "develop a national benchmark that accurately estimates acquisition cost and encourages states to consider it when determining Medicaid reimbursement for prescription drugs."¹¹ The OIG noted that this recommendation would "eliminate states' reliance on the inflated published prices that cause Medicaid and its beneficiaries to pay too much for certain drugs." The CMS concurred with the recommendation and solicited a vendor to develop this national benchmark. However, the timeline for the availability of this benchmark from the CMS has not been definitively established. In any case, since it is widely known that the AWP benchmark does not represent prices paid by the pharmacy, it is appropriate to move to an alternative benchmark rather than relying on a fraudulent benchmark.

F. Iowa Stakeholder Involvement

lowa Medicaid hosted a stakeholder meeting in October 2011 with the purpose of soliciting feedback and ideas from the stakeholders regarding proposals for the replacement of AWP in Iowa Medicaid's overall pharmacy reimbursement methodology. Iowa Medicaid also added a webpage to the Iowa SMAC website, which afforded stakeholders the opportunity to download information regarding this meeting and other subsequent updated materials. The stakeholders invited to the October meeting

¹⁰ Western Medicaid Pharmacy Administrators Association annual conference. September 2010.

¹¹ "Replacing Average Wholesale Price: Medicaid Drug Payment Policy." Office of Inspector General. July 2011.

included the Iowa Pharmacy Association, national independent and chain drug store associations, all Iowa Medicaid enrolled pharmacies, pharmaceutical manufacturers and their trade organization, and all enrolled pharmacy providers who elected to receive information regarding the Iowa Medicaid pharmacy program. Stakeholders participated in the October stakeholder's meeting via onsite attendance and through a telephone conference line. Attendees were able to interact with the Iowa Medicaid Enterprise ("IME") staff to discuss the proposed recommendation and offer feedback.

During the meeting and in follow-up communication, stakeholders presented their preference for brand drug reimbursement that is based on WAC, with no change in the generic reimbursement or current dispensing fee of \$6.20 per claim. The National Association of Chain Drug Stores ("NACDS") reported analysis suggesting that WAC was approximately AAC+2%, a result that was not verifiable by the Department. A request was made by the IPA and the NACDS to consider a WAC-based reimbursement for brand drugs that would maintain the level of reimbursement currently provided with the AWP-based rates. Specifically, the IPA recommended that the new reimbursement rate be set at WAC plus 5.8%. However, there are issues related to the adoption of this recommendation.

Because WAC is not based on actual drug costs, it is not reflective of actual drug costs and is open to manipulation as was the AWP.¹² If WAC is used for the reimbursement of brand drugs while the reimbursement for generic drugs remain based on SMAC rates, different pricing benchmarks would be used for brand drugs and their generic counterparts. Additionally, not all generic drugs have an applicable SMAC rate. Therefore, drugs without an applicable SMAC rate would reimburse using a WAC-based rate.

The use of different pricing benchmarks for brand and generic drugs introduces additional complexity in the claims adjudication system: WAC-based rates for brand drugs, AAC-based SMAC for generic drugs, and a third benchmark for generic drugs without SMAC rates. Difficulties include system modification and maintenance, auditing and tracking activities, and general clarity of the reimbursement policy. With regards to the dispensing fee, though the stakeholders do not advocate a change in the dispensing fee if reimbursement is based on WAC, CMS may mandate that the dispensing fee be adjusted to reflect a cost of dispensing study. Some cost of dispensing studies have shown that pharmacies spend an estimated \$10 to \$11 to dispense a prescription, in addition to the cost of the drug product.¹³ The stakeholders advocate completion of a cost of dispensing study but voiced concern that if completed the study must include comprehensive reporting of the actual cost of dispensing a drug, which is a recommendation with which the Department concurs.

¹² "Post AWP Pharmacy Pricing and Reimbursement." American Medicaid Pharmacy Administrators Association and the National Association of Medicaid Directors. June 2010.

¹³ "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies." Grant Thornton, Jan 2007; "Cost of Dispensing Prescription Drugs in Alabama. Final Report." Health Information Designs, Jan 6, 2010.

The determination of WAC values is not transparent, which lessens the defensibility of using WAC for reimbursement purposes. In addition, states that consider resorting to WAC-based EAC formulas face the potential of increased costs to the Medicaid agency if a cost neutral WAC reimbursement is implemented and the CMS requires a concurrent increase in the dispensing fee. Some stakeholders noted that certain states that have changed their reimbursement methodology have adopted a WAC benchmark. However, the IME staff noted that such states had historically used First DataBank. The IME staff noted that changing publishing companies (i.e., changing from First DataBank to Medi-Span) is not an easy task and typically requires a change in administrative rules. Therefore, states that historically relied on First DataBank information had little to no other choice but to pick an existing First DataBank benchmark once that company stopped publishing the AWP benchmark in September 2011. Moreover, some larger states, including New York and California, have recently modified their laws to allow state-specific estimates of average acquisition cost benchmarks, in addition to the states of Alabama, Idaho and Oregon who already use the AAC benchmark.

At the stakeholder meeting, the IME forwarded the proposition of expanding the use of the SMAC into other areas to create a state-specific AAC benchmark. Various stakeholders expressed their concerns with the possibility of using AAC-based reimbursement. A memo sent from the NACDS to the IME listed the timeliness and confidentiality of the AAC as major areas of concern. In the meeting, the IME explained the update process and frequency used for the AAC methodology in other Medicaid programs. In the other states, AAC rates for brand drugs are updated weekly, with the update frequency of generic drug AAC rates varying per state policy. Each program has a provider help desk where updated AAC rates can be presented to the state in as little as a day. Regarding protecting the confidentiality of pharmacy price information, there are contractual obligations that bind the rate setting vendor to maintain the confidentiality of the materials submitted through the surveys. The current Iowa Medicaid contractor has performed many acquisition cost surveys in Iowa since 2004 and has a proven record of maintaining confidentiality for Iowa pharmacies.

An early recommendation by the IME was the requirement of drug manufacturers to submit AMP data to the IME to provide external validation of pharmacy acquisition cost data submitted by pharmacies. CMS receives AMP data from drug manufacturers, but the data is not currently provided to Iowa Medicaid or most other state Medicaid agencies for use in reimbursement validation. Because AMP data reflects prices for actual sales between the manufacturer and wholesaler, AMPs provide a more understandable and transparent comparison benchmark than AWP or WAC. Therefore, AMPs are less vulnerable to manipulation.

Stakeholders expressed opposition to the use of AMPs to validate submitted acquisition costs. In the October 2011 paper titled, "Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices," the OIG reported that AMP had a consistent relationship with acquisition costs for brand drugs, which allows the AMP to be used in

the validation of submitted brand drug acquisition costs.¹⁴ The OIG also found AWP and WAC to have consistent relationships with brand acquisition cost as well.

Based on stakeholders' concerns with the use of the AMP for validation purposes as voiced through subsequent discussions and the experience of other state Medicaid agencies in the enforcement of submission of AMP data to the Medicaid programs, the required submission of AMP data is no longer a proposed recommendation by the IME. However the IME will continue to research methodologies that could be utilized to validate submitted pharmacy acquisition cost data.

In addition to the October 2011 meeting, the Department released the draft report to stakeholders, and a follow up meeting was held on December 6, 2011, to receive further comments. Additionally, the Department received even more comments electronically.

G. Potential AWP Replacement Benchmarks

The American Medicaid Pharmacy Administrators Association ("AMPAA") and the National Association of State Medicaid Directors ("NASMD") published a white paper in November 2009 that summarized the organizations' opinions regarding the available options for a replacement of AWP for drug reimbursement. The white paper was developed by a committee which was formed and comprised of thirteen state Medicaid pharmacy directors, with technical assistance provided by representatives of First DataBank, Inc., a drug pricing compendium and included representatives of NASMD. In this white paper, the committee recommended the establishment of a single national benchmark for pharmacy reimbursement based on actual acquisition cost data. The following are the discussed potential benchmarks to replace AWP and issues with their ability to be used in this capacity.

- 1) Average Acquisition Cost ("AAC")
 - a. AAC is the average amount paid by pharmacies to suppliers (e.g., wholesalers, manufacturers) for brand and generic drugs. AAC would be obtained from pharmacies or wholesalers through invoice collection.
 - b. Pros: Reflective of Iowa pharmacy drug costs; transparent process to calculate rates; not susceptible to manipulation.
 - c. Cons: Would reflect past transactions; would not be universally available for all national drug codes ("NDCs"); would require a contract amendment with Provider Audit and Rate Setting for approximately \$131,500 total funds (\$65,750 state funds) annually, depending on the final policy decisions.
 - d. Estimated annual fiscal impact to lowa Medicaid for reimbursing ingredient cost with AAC methodology:
 - i. AAC plus \$10.00 Dispensing Fee (-\$4.9 M) total funds
 - ii. AAC plus \$11.10 Dispensing Fee (-\$0.1 M) total funds
 - (See Table 2 of the appendix for fiscal estimate detail.)
- 2) Wholesale Acquisition Cost ("WAC")

¹⁴ "Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices." Office of Inspector General. October 2011.

- a. WAC is purported to be the manufacturers' catalog or list price for drugs to wholesalers. Wholesalers eventually sell these drugs to pharmacies. WAC is determined by the manufacturer.
- b. Pros: No additional cost to obtain the WAC; found to have a consistent relationship to brand drugs costs.
- c. Cons: Not more transparent than AWP because the WAC cannot be audited back to the transactions they are supposed to represent; would not be universally available for all NDCs; susceptible to manipulation due to the lack of transparency; not reflective of drug costs for generic drugs.
- d. Estimated annual fiscal impact to lowa Medicaid for reimbursing ingredient cost with WAC plus methodology:
 - i. WAC plus \$6.20 Dispensing Fee (-\$627,000) total funds

ii. WAC plus \$10.00 Dispensing Fee +\$16.4 M total funds

(See Table 2 of the appendix for fiscal estimate detail.)

- 3) Weighted Average Manufacturer Price ("AMP")
 - a. AMP is purported to be the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP is reported by manufacturers. It was redefined by the Affordable Care Act. CMS will publish the weighted AMP on a monthly basis.
 - b. Pros: Would be available from the federal government, presumably at no additional cost to the program. Calculation is defined in the Social Security Act so it is transparent. Based on actual sales data. OIG found AMP to have a consistent relationship to brand drug costs.
 - c. Cons: Weighted AMP is not available yet so cannot be evaluated as a reimbursement option at this time; reflective of transactions between manufacturers and wholesalers so an adjustment is needed to make it applicable to pharmacy costs.
- 4) National Average Drug Acquisition Cost ("NADAC")
 - a. NADAC is a not-yet-available benchmark that CMS will publish on its website. Like the Iowa Medicaid SMAC rates, the NADAC will utilize drug costs collected from pharmacies through a survey.
 - b. Pros: Would be available from the federal government, presumably at no additional cost to the program; would be reflective of national pharmacy drug costs.
 - c. Cons: Due to the unavailability of this benchmark, it cannot be evaluated to determine if it is appropriate to use in reimbursement for Iowa Medicaid claims; CMS has not announced a timeline for when the NADAC will be available.
- 5) State MAC ("SMAC")
 - a. SMAC is a state-level upper reimbursement limit applied to generic drugs. Determination of these reimbursement rates are individualized per state. SMAC would be calculated by Medicaid agencies or their contractors. SMAC rates in Iowa are based on AAC, though other states may use different baseline values for their SMAC rates.
 - b. Pros: AAC-based SMAC rates are familiar to Iowa pharmacies; rates are reflective of Iowa pharmacy drug costs.

- c. Cons: Dependent upon another benchmark for determination (e.g., AAC or WAC).
- 6) Average Sales Price ("ASP")
 - a. ASP is purported to be the average price for drugs as reported to CMS by manufacturers. CMS calculates ASP from manufacturer-reported data.
 - b. Pros: Would be available from the federal government, presumably at no additional cost to the program.
 - c. Cons: Currently only available for a limited number of drugs covered by Medicare Part B so is very limited in scope; In addition, the ability to audit the manufacturer-reported data is limited due to the confidentiality of the sales prices
- 7) Predictive Acquisition Cost ("PAC")
 - a. PAC is a yet-to-be-published benchmark that utilizes predictive analytics to estimate the acquisition cost of drugs.
 - b. Pros: Reportedly would be available for all NDCs
 - c. Cons: This benchmark is unproven and unavailable; The methodology by which acquisition costs are predicted is not transparent; The attainment and integration of the benchmark may require additional cost to the Department

Of the potential AWP replacements, AAC best accomplishes the goals of the Medicaid statute requirement of "estimated acquisition cost."

III. Recommended Pharmacy Reimbursement Replacement Plan for Iowa Medicaid

With consideration of the options available to the state at the time of the writing of this report, and the suggestions of the stakeholders, the following recommendation is presented for the replacement of the AWP-based pharmacy reimbursement methodology.

Recommendation: Replace the current AWP-based reimbursement methodology with an AAC-based reimbursement methodology that is budget-neutral to current overall reimbursement.

One of the goals of the recommendation is to shift pharmacy reimbursement to a transparent methodology that reflects the price that providers pay to acquire drugs. The use of the AAC for determining reimbursement rates meets this goal. Therefore, the Department proposes to replace the AWP-based reimbursement methodology with an AAC-based reimbursement methodology. Drug acquisition costs will be collected from pharmacies through a survey of invoices, and those invoices will reflect prices paid for drugs. In order to ensure that AACs reflect prices from community retail pharmacies, 340B pharmacies, mail order pharmacies, and closed door pharmacies would be excluded from the pharmacy acquisition cost survey.

Although the use of WAC would not introduce additional cost to the Medicaid program, issues exist with the use of this benchmark for reimbursement. Manufacturers establish WACs for their pharmaceuticals through non-transparent means, which leaves the benchmark just as susceptible to manipulation as the highly discredited AWP benchmark. Current published WACs do have a consistent relationship to brand drug costs but lack any consistent relationship with generic drug costs. Shifting reimbursement to a benchmark that lacks transparency and is vulnerable to manipulation does not address the issues that were present with the AWP. Refer to Table 1 in the appendix for additional comparisons between AAC and WAC.

Another advantage to this proposed recommendation is that the Iowa SMAC program currently utilizes the average drug acquisition cost for establishing reimbursement rates. Therefore, Iowa pharmacy providers are already familiar with the procedures for submitting the requested information. Drug cost surveys require minimal administrative effort and can be completed by non-pharmacist personnel. However, AAC-based reimbursement rates will need to be adjusted on a weekly basis to reflect changes in manufacturer-reported published prices, which increases the workload. In addition, a provider help desk will be maintained and rate inquiries that warrant adjustment will need to be addressed.

The establishment and maintenance of an AAC reimbursement program can be accomplished through the expansion of the existing AAC-based SMAC program, if this recommendation is accepted. Acquisition costs for brand, generic and OTC drugs are already collected in the pharmacy surveys. In addition, supporting functions such as a provider help desk and website are in place. There will be an additional cost for the added scope of services, though this cost would take into account the fact that established operations already exist. Because AWP and WAC do not reflect actual drug costs, the alternatives of maintaining AWP-based ingredient reimbursement or switching to a WAC-based reimbursement does not result in an estimate of the price generally and currently paid by providers for a drug, as defined in the federal statute. As previously mentioned, the timetable for the publication of the NADAC has not been defined. Therefore, a reimbursement change based on the NADAC cannot be evaluated.

The WAC benchmark's lack of reference to actual drug costs means the state cannot assess true prices paid by pharmacies and, therefore, cannot avail itself of the opportunity of lowering inflated prices when they exist. Should the WAC benchmark be considered further, additional program costs must be taken into consideration, including the establishment of prices for drugs for which no WAC is available. Processes would need to be developed and maintained to establish reimbursement rates for drugs without WACs. Providers would not have the ability to have individual WAC-based reimbursement rates adjusted when irregularities in price are identified because the Department would not be capable of varying published WAC rates. The IPA and the NACDS requested a reimbursement rate of WAC+5.8%, which may represent a budget-neutral or increase over the current

AWP-12% reimbursement. Coupled with a potential increase in the dispensing fee, this option could result in an increase in cost to the state if the WAC plus reimbursement is not set below the current AWP-based reimbursement levels to offset any increase to the dispensing fee.

The estimated cost of expanding the current AAC-based SMAC program to incorporate support of brand and OTC drug reimbursement is \$131,500 total funds (\$65,750 state funds) annually. This additional expense encompasses the establishment and maintenance of AAC rates, support of the provider help desk, and the administrative functions of rate file transfers and website maintenance. Shifting from AWP-based rates to AAC-based rates has resulted in ingredient cost savings far above the AAC program operations costs in other states that implemented this reimbursement approach. The level of savings is determined by program policy and baseline reimbursement. If the dispensing fee would need to be increased, any savings from the ingredient cost portion of reimbursement would help offset the additional cost.

The IME is proposing reimbursement to be established as budget-neutral to the current overall reimbursement for drug ingredient cost plus dispensing fee. This approach will minimize the impact of this change on the overall provider community and on patient access to drugs, while adjusting reimbursement to reflect the cost of drugs through an AAC-based methodology and a dispensing fee supported by a cost of dispensing study. A dispensing fee in the range of \$11.10 has been projected, through modeled fiscal estimates, to result in an estimated fiscal impact of a net savings of approximately \$100,000 total annually. (See Table 2 of the appendix for fiscal estimate detail.) The dispensing fee used in the models is for illustrative purposes only. The actual dispensing fee would be determined after completion of a cost of dispensing study. Any change to the reimbursement methodology and dispensing fee is subject to CMS approval.

Tasks Associated with Change in Reimbursement

1) Perform a cost of dispensing study to evaluate the reasonableness of the current lowa dispensing fee.

In addressing the goal of evaluating the dispensing fee component of pharmacy reimbursement, the Department proposes to perform an evaluation of the reasonableness of the current Iowa dispensing fee. The recommendation for the process by which Iowa costs to dispense would be measured has not been finalized. Options include performing an Iowa-specific cost of dispensing study, or seeking CMS approval to utilize recent cost of dispensing studies performed in other states.

CMS recently approved the State Plan Amendment for Alabama Medicaid for a reimbursement plan that included ingredient cost reimbursement at the AAC with a \$10.64 dispensing fee. The dispensing fee was supported by a recent cost to dispense study. The State Plan Amendment for Oregon Medicaid was also recently approved. It included an ingredient cost reimbursement at the AAC with a tiered

dispensing fee that ranges from \$9.68 to \$14.01, depending on prescription volume of the pharmacy. Many dispensing fee studies result in a cost to dispense in the \$10-\$12 range. Currently, the professional dispensing fee paid by the Iowa Medicaid program for each prescription fill is the lower of \$6.20 or the pharmacy's usual and customary fee. 441 Iowa Admin. Code § 79.1(8)(g).

2) Remove Department of Justice ("DOJ") reimbursement rates from the reimbursement methodology.

In 2000, the Department of Justice ("DOJ") and the National Association of Medicaid Fraud Control Units ("NAMFCU") published revised AWPs for a few hundred NDCs of injectable, infusion, and inhalation drugs based on actual collected wholesale prices. As recommended by the NAMFCU, the revised AWPs have been utilized for the reimbursement of the respective drugs. However, these rates have not been maintained and updated to reflect current drug costs. Because the revised AWPs no longer reflect drug prices, the Department recommends the removal of these rates from the reimbursement methodology.

3) Perform a formal analysis to evaluate maintaining FUL rates in the reimbursement methodology.

CMS recently published draft AMP-based FUL rates for public review and comment. Preliminary reports have stated a concern with the number of AMP-based FUL rates that fall below pharmacy acquisition costs. The IME is currently conducting analyses to evaluate these FULs. In evaluation of maintaining the FUL in the pharmacy reimbursement methodology, consideration will be given to the results of these analyses and the FUL update process, in light of the growing number of current FULs that no longer cover drug acquisition costs. As required, the Medicaid program would need to maintain reimbursement at or below the aggregate FUL reimbursement. At least one other Medicaid program has implemented the removal of the FUL from its reimbursement methodology, while maintaining meeting the aggregate FUL, with CMS approval.

4) Review and clarification of the requirement of 340B pharmacies to submit 340B acquisition cost on pharmacy claims.

The OIG published a report in June 2011 titled "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs." In this report, the OIG recommended that "CMS direct states to create written 340B policies and work with HRSA to share 340B ceiling prices with states and improve the accuracy of the Medicaid Exclusion File." The 340B Drug Discount Program ("340B Program") requires drug manufacturers to provide covered outpatient drugs to certain eligible health care entities, known as covered entities, at or below statutorily defined discount prices. When reimbursing for 340B purchased drugs, state Medicaid agencies have a responsibility to accurately reimburse covered entities and appropriately claim Medicaid rebates from drug manufacturers. The Department recommends clarifying Iowa Medicaid's 340B policy by working with CMS to include specific guidance to 340B providers in regard to the need to submit their 340B acquisition costs for their 340B drug claims to Medicaid.

Summary

A conversion from AWP-based reimbursement to WAC-based reimbursement does not resolve the potential for manipulation of the pricing benchmark due to the lack of transparency regarding the determination of the WAC. Due to the uncertainty regarding the availability of the CMS NADAC benchmark, or the ability of the IME to utilize the rates once they are developed, the Department recommends that the replacement methodology plan should include consideration of a state-level approach as an interim solution. The Medicaid programs in Alabama, Oregon, and Idaho currently utilize state-established AACs for pharmacy reimbursement of brand and generic drugs.

CMS has indicated to states that a change to acquisition cost-based reimbursement for drug ingredients should be coupled with an evaluation of the dispensing fee to determine the reasonableness of this portion of the reimbursement. Any State Plan Amendments submitted should address both aspects of pharmacy reimbursement, with the dispensing fee evaluated through a cost of dispensing study of lowa pharmacies.

Appendix

| | AAC | WAC |
|--|---|---|
| Reflective of drug costs | Yes. AAC is based on costs collected directly from Iowa pharmacies showing amounts paid to wholesalers or manufacturers for drugs. Therefore, it is reflective of the cost of drugs. | No. WAC does not have a clear and defined basis for determination so it cannot be concluded that WAC is reflective of drug costs. An October 2011 OIG report found that although WAC had a consistent relationship with brand drug cost, it did not have a relationship to generic drug costs. |
| Transparent | Yes. It is clear from where the data to determine the AAC originated. The data is obtained from Iowa pharmacy invoices. | No. The WAC is provided by the manufacturer, but there is no defined method by which the WAC is determined. |
| Accessible | Yes. The AAC rates are sent to lowa's fiscal agent and loaded into the claims payment system. The rates are also published on the Iowa SMAC website for providers to access. | Yes, the WAC is published on the Medi-Span files and loaded into the claims payment system by Iowa's fiscal agent. |
| Comprehensive of all NDCs | No. AAC rates are established for drugs where invoice costs were reported. Aside from the AWP, no benchmark is comprehensive of all NDCs. AAC provides reimbursement for the most commonly utilized drugs, which accounts for the large majority of Medicaid drug spend. | No. Not every manufacturer reports a WAC for their drugs. This is particularly true for generic drugs, which have fewer WAC rates than brand drugs. |
| Timeliness | Yes. AAC rates for brand drugs are updated weekly and provider rate reviews can result in daily rate adjustments. In addition, drug price changes confirmed in other states are applied in Iowa. | Yes. WAC updates are reported on updated Medi-Span files. |
| Resistant to Manipulation | Yes. Providers submit invoices from the wholesaler that gives evidence of actual prices paid for drugs. | No. There is no transparency in the determination of WAC rates. Therefore, there is no way to determine if the WAC has been manipulated in the future. |
| Ability to Address Provider Appeals | Yes. Since AAC rates are established based on provider drug costs, providers can contact the Help Desk to request reviews of AAC rates. When appropriate for change, particular AAC rates can be updated. | No. Since WAC rates are determined by the manufacturer, there is no state-level ability to modify the reimbursement based on WAC rates for individual drugs. |

Table 1: Comparison of AAC and WAC

¹Reimbursement with this benchmark is the WAC plus a percentage.

| | | Option A | Option B | Option C | Option D |
|---------------------------------------|--|--|--|--|---|
| Reimbursement Expenditure Category | Current | Change AWP to WAC; DF Remains the Same | Change AWP to WAC; DF Increases to \$10.00 ² | Change AWP, SMAC & OTC MAC to AAC; DF Increases to \$10.00 ³ | Cost Neutral Change AWP, SMAC & OTC MAC to AAC DF Increases to \$11.10 ⁴ |
| Brand Drug Ingredients | Lower of AWP -12% or Usual & Customary (U&C) | Lower of WAC +5.8% or U&C +\$345,000 | Lower of WAC +5.8% or U&C +\$345,000 | Lower of AAC or U&C (-\$13.4 M) | Lower of AAC or U&C (-\$13.4 M) |
| Generic Drug Ingredients | Lower of AWP -12% ⁵ , SMAC, FUL, U&C | Lower of WAC +5.8%, SMAC, FUL or U&C (-\$910,000) | Lower of WAC +5.8%, SMAC, FUL or U&C (-\$910,000) | Lower of AAC, FUL or U&C (-\$7.8 M) | Lower of AAC, FUL or U&C (-\$7.8 M) |
| Over-The-Counter (OTC) Ingredients | Lower of MAC (Median of AWP) or U&C | Lower of MAC (Median of WAC) or U&C + \$48,000 | Lower of MAC (Median of WAC) or U&C + \$48,000 | Lower of AAC or U&C (-\$735,000) | Lower of AAC or U&C (-\$735,000) |
| Specialty Drug Ingredients | Lower of AWP -17% or U&C | Lower of WAC -0.5% or U&C (-\$110,000) | Lower of WAC -0.5%, or U&C (-\$110,000) | 6 | 7 |
| Dispensing Fee (DF) | \$6.20 | \$6.20 N/A | \$10.00 +\$17.0 M | \$10.00 +\$17.0 M | \$11.10 +\$21.8 M |
| Estimated Total Fiscal | N/A | (-\$627,000) | +\$16.4 M | (-\$4.9 M) ⁸ | (-\$0.1 M) ⁹ |

Table 2: Estimated Annual Fiscal Impact of Selected Reimbursement Options¹

¹ Fiscal estimates are presented in State and Federal dollars. Annual units used to compute the fiscal estimates were based on claims processed between 10/1/2010 and 9/30/2011.

² The dispensing fee used in the models is for illustrative purposes only. The actual dispensing fee would be determined after completion of a cost of dispensing study.

³ Ibid.

⁴ Ibid.

⁵ AWP minus 12% is used for drugs that do not meet the criteria to have a SMAC or FUL applied. About 8% of expenditures do not have a SMAC or FUL.

⁶ Acquisition cost data (AAC) available is limited to approximately 30% of all specialty drugs. Because of this limitation, we are unable to estimate the fiscal impact. For the 30% of specialty drugs that we do have acquisition cost data, the fiscal impact was (-\$490,000). ⁷ Ibid.

⁸ Fiscal estimate for Option C does not include cost savings associated with a change to specialty drug reimbursement. Refer to footnote 6.

⁹ Fiscal estimate for Option D does not include cost savings associated with a change to specialty drug reimbursement. Refer to footnote 7.

| 1. | | Option A | Option B | Option C | Option D |
|---------------------------------------|---|---|--|--|---|
| | | | | | Cost Neutral |
| Reimbursement Expenditure Category | Current | Change AWP to WAC; DF Remains the Same | Change AWP to WAC; DF Increases to \$10.00 ² | Change AWP, SMAC & OTC MAC to AAC; DF Increases to \$10.00 ³ | Change AWP, SMA0 & OTC MAC to AAC DF Increases to \$11.10 ⁴ |
| | Lower of AWP | | | | |
| Brand Drug Ingredients | -12% or Usual & | Lower of WAC +5.8% or U&C | Lower of WAC +5.8% or U&C | Lower of AAC or U&C | Lower of AAC or U&C |
| | Customary (U&C) | +\$345,000 | +\$345,000 | (-\$13.4 M) | (-\$13.4 M) |
| | | | | | |
| Generic Drug Ingredients | Lower of AWP -12% ⁵ , SMAC, | Lower of WAC +5.8%, SMAC, FUL | Lower of WAC +5.8%, SMAC, FUL | Lower of AAC, FUL or U&C | Lower of AAC, FUL or U&C |
| | FUL, U&C | or U&C (-\$910,000) | or U&C (- \$910,000) | (-\$7.8 M) | (-\$7.8 M) |
| | | Lawar of MAG | | | |
| Over-The-Counter (OTC) Ingredients | Lower of MAC (Median of AWP) or U&C | Lower of MAC (Median of WAC) or U&C +\$48,000 | Lower of MAC (Median of WAC) or U&C + \$48.000 | Lower of AAC or U&C (-\$735,000) | Lower of AAC or U&C (-\$735,000) |
| | | | | | |
| Specialty Drug Ingredients | Lower of AWP -17% or U&C | Lower of WAC -0.5% or U&C (- \$110,000) | Lower of WAC -0.5%, or U&C (- \$110,000) | 6 | 7 |
| | | | | | |
| Dispensing Fee (DF) | \$6.20 | \$6.20 N/A | \$10.00 +\$17.0 M | \$10.00 +\$17.0 M | \$11.10 +\$21.8 M |
| Estimated Total Fiscal | N/A | (-\$627,000) | +\$16.4 M | (-\$4.9 M) ⁸ | (-\$0.1 M) ⁹ |

Table 2: Estimated Annual Fiscal Impact of Salastad Raimburgament Options¹

⁵ AWP minus 12% is used for drugs that do not meet the criteria to have a SMAC or FUL applied. About 8% of expenditures do not have a SMAC or FUL. ⁶ Acquisition cost data (AAC) available is limited to approximately 30% of all specialty drugs. Because of this limitation, we are unable to estimate the fiscal impact. For the 30% of specialty drugs that we do have acquisition cost data, the fiscal impact was (-\$490,000).

⁷ Ibid.

⁸ Fiscal estimate for Option C does not include cost savings associated with a change to specialty drug reimbursement. Refer to footnote 6.
⁹ Fiscal estimate for Option D does not include cost savings associated with a change to specialty drug reimbursement. Refer to footnote 7.

¹ Fiscal estimates are presented in State and Federal dollars. Annual units used to compute the fiscal estimates were based on claims processed between 10/1/2010 and 9/30/2011.

² The dispensing fee used in the models is for illustrative purposes only. The actual dispensing fee would be determined after completion of a cost of dispensing study.

³ Ibid.

⁴ Ibid.

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