American Medicaid Pharmacy
Administrators Association
And
The National Association of
Medicaid Directors

Executive Summary
And
White Paper

Post AWP Pharmacy Pricing and Reimbursement

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EXECUTIVE SUMMARY

Introduction

For nearly forty years, a standard pricing benchmark employed for the reimbursement of drugs, for both public and private payors, has been the "Average Wholesale Price" or "AWP," a value based on manufacturer-reported information and compiled by commercial drug pricing compendia. The recent determination of major drug pricing compendia to cease publication of AWP no later than September, 2011 creates a challenge and an opportunity for state Medicaid programs: states must find a new drug pricing standard and do so immediately, so that necessary adaptations, in law, regulation and system design, can be accomplished in time.

Recognizing this exigency, the American Medicaid Pharmacy Administrators Association (AMPAA) commissioned a Working Group to review this subject, and convened a three-day conference in Chicago from October 12-14, 2009. The committee was comprised of thirteen state Medicaid pharmacy directors, with technical assistance provided by representatives of First DataBank, Inc., a drug pricing compendium. Subsequently, information collected from the AMPAA conference was presented to the National Association of Medicaid Directors (NASMD) during a meeting in Washington D.C. on November 9, 2009, and upon NASMD concurrence, the Working Group was expanded to include representatives from NASMD as well. The attached White Paper report establishes the standards employed by the Working Group, outlines pertinent issues and potential problems, and sets forth those conclusions and recommendations upon which consensus was reached. The report is intended as a starting point for engaged discussion regarding a post-AWP pricing standard and a call to action for all affected parties. The Working Group intends to continue its efforts to foster the involvement by the states in the benchmark development process and we look forward to the cooperative efforts of both state and federal representatives, as well as other stakeholders, in this endeavor.

Summary of Committee Recommendations

I. Establishment of a single national benchmark for pharmacy reimbursement based on actual acquisition cost data

- **A single national benchmark, as opposed to a variety of different standards, will be more efficient, less prone to error and more consistent with the current national effort at healthcare information standardization –** A multiplicity of pricing standards invites confusion, places a greater burden on providers, and creates more complexity in the reimbursement process than a single, agreed-upon value.

- **A price benchmark based on actual average acquisition cost data most clearly fulfills legal and practical requirements and has great**

potential. However, obtaining a valid source of acquisition cost information will require strict definitions, legal reporting obligations, and the identification of a data gathering and reporting process – Using true average cost data complies most literally with federal law and, with a reasonable dispensing fee, is both equitable and legally defensible. Its development, however, may require: changes in state and federal law, the imposition of reporting obligations on wholesalers, pharmacies, or manufacturers; Medicaid State Plan Amendments; and a revised process for price reporting, ideally one that was coordinated among groups of states if not all states.

- **WAC accompanied by a well-designed MAC program may provide an interim alternative but should only be viewed as a temporary solution –** "Wholesale Acquisition Cost" prices are currently available for many, but not all drugs. WAC may be susceptible to the same concerns that rendered AWP ineffective: it is a manufacturer-reported value not readily amenable to audit, and there is no reason for confidence that it could not ultimately be inflated well beyond any actual market price. Particularly since it has been defined in federal law as an "undiscounted list price" WAC would require continuous adjustments (markups or markdowns) by states based on acquisition cost surveys.

II. Efforts must begin now to establish the new benchmark, overcome resistance, and implement change

- **Immediate action is necessary –** With less than two years available before the disappearance of AWP, every effort must be made to accelerate progress toward a solution -- especially considering the host of necessary changes to statute, regulation, IT systems, contractual relations and reporting procedures. To meet the two year timetable, the states, CMS, providers and all other stakeholders must immediately begin working cooperatively and diligently toward the implementation of a new benchmark.

- **Any replacement formula or standard will meet with resistance and the inertia opposing change must be overcome –** All the potential resolutions considered by the Working Group presented at least some problematic aspects, and it is reasonable to expect that any new benchmark will meet with some opposition. Reaching a successful result will therefore require the political will to overcome this opposition when a well-designed replacement has been identified. Formation of a national coalition of stakeholders is a reasonable first step toward identifying stakeholder challenges and working toward compromise.

- **It is in the interest of the states to act quickly on their own behalf to identify a new drug price benchmark before other stakeholders do so –** It has been demonstrated that a price standard adopted early can achieve substantial acceptance in the market. By identifying the post-AWP replacement quickly, the states have a unique opportunity to design a standard which meets their needs.

INTRODUCTION

Historically, Average Wholesale Price ("AWP") has been the generally accepted drug payment benchmark for many payers because it has been the only price readily available for all drugs. Originating in the California Medicaid program in the late 1960's as a price derived from surveys of major drug wholesalers, AWP has since evolved into a calculated value based on information supplied solely by drug manufacturers. Over time, AWP has been subject to differing and variable interpretations, as evidenced by the numerous and continuing legal actions relating to its calculation and use.

The primary sources of AWP are private drug data compendia, with most pharmacies and third party payers using First Data Bank or Medi-Span as their primary source. Both First Data Bank and Medi-Span have announced decisions to cease the publication of AWPs for drugs no later than September of 2011. Stakeholders will need to identify a new pharmacy reimbursement benchmark to fill the vacancy which AWP's departure will leave.

Given the substantial degree to which any change to a new drug pricing benchmark will require stakeholders to modify computer systems, renegotiate contracts and otherwise adapt, this two-year deadline is for all intents and purposes imminent. Affected parties, particularly Medicaid programs that may require legislative and regulatory action to accommodate a new and different benchmark, must therefore begin to act now to develop a replacement pricing standard. In recognition of this exigency, a Working Group of the American Medicaid Pharmacy Administrators Association (AMPAA) was convened in October 2009 to consider this subject. Subsequently, information collected from the AMPAA conference was presented to the National Association of Medicaid Directors (NASMD) in November 2009, and upon NASMD concurrence, the Working Group was expanded to include representatives from NASMD as well. This White Paper review of the issues, obstacles and potential resolutions related to the termination of AWP reporting represents the analysis and conclusions of the Working Group.

In its assessment, the Working Group was guided by the following fundamental principles:

1. **The touchstone for any replacement drug price must be the federal Medicaid standard –** Pursuant to federal regulation[*], brand name drugs must be reimbursed at the "lower of estimated acquisition costs plus reasonable dispensing fees established by the [single state] agency; or usual and customary charges." "Estimated acquisition costs" are further defined as "the best estimate of the price generally and currently paid by providers in the most frequently purchased package size."[**]

[*] 42 CFR 447.512. Generic drugs are generally limited to Federal Upper Limit price calculated by the Centers for Medicare and Medicaid Services.
[**] 42 CFR 447.502

Consequently, any new price benchmark must be one that bears a genuine relationship to what pharmacy purchasers are actually paying for drugs.

2. **Inaction by states in defining a new price term will necessarily mean that other stakeholders will provide that definition –** In simple terms, states will either identify a new pricing model that reflects their interests and concerns or they will likely have to adapt to a benchmark designed by others in the pharmaceutical marketplace who do not necessarily share the states' values. It is consequently incumbent on the states to act both collectively and for themselves, and to do so before an alternative, less satisfactory benchmark achieves market acceptance.

3. **The replacement standard must correspond to outpatient *pharmacy* costs, and not to prices paid by other purchasers –** Purchasers, **s**uch as hospitals, physicians, pharmacy benefit managers, 340 B facilities or federal supply schedule purchasers, are frequently offered prices unavailable to the community pharmacy class of trade. An equitable reimbursement standard for pharmacies must be derived from information specific to each class.

4. **The replacement standard should be sustainable for the foreseeable future, *i.e.*, it should be designed insofar as possible to avoid problems that would require reevaluation or replacement –** There is little value in arriving at a new drug pricing benchmark that itself would need to be supplanted five years from now. While the careful deliberation of potential issues that might arise cannot guarantee success, general prerequisites for sustainability -- the necessity of well-defined terms, the utility of legal reporting obligations, the need for an identifiable relationship to real-world evidence, the importance of creating proper incentives, the crucial prerequisite of a feasible verification process – must be put into effect in the design of a new price standard.

5. **To be reliable, any price information that is used to set a new benchmark must be acquired pursuant to a legal obligation to report a timely well-defined value –** Although practically speaking some sort of reporting is necessary for drug products to be reimbursed, there is currently no statutory requirement to report a particular price type – Wholesale Acquisition Cost (WAC), Suggested Wholesale Price (SWP) or Direct - and no consequence for failing to report one. If the states are to obtain true and useful information, whatever entity is communicating price data – whether a manufacturer, wholesaler or pharmacy – must do so under a unified federal/state legal requirement to provide explicitly defined data.

6. **A unified national drug pricing benchmark will be less prone to confusion, will more effectively serve as an AWP replacement and more completely fulfill current national efforts toward healthcare information harmonization –** While it is conceivable that states could adopt different standards to be used as a basis for drug pricing – one state employing manufacturer-reported data, another relying on a pharmacy survey and a third looking to wholesaler invoices – the greater complexity of such a situation introduces a potential for error. This is not to say that a common

benchmark presupposes identical payment values, and states as well as any other payors could elect to reimburse at the benchmark value plus or minus a factor and could make variable adjustments for different classes of purchasers. But in a period in which national healthcare legislation and reform efforts are all directed toward standardization, information technology compatibility and the elimination of variability in medical claims submission, the development of a single drug pricing benchmark is the only prudent option.

CURRENT STATUS OF STATE MEDICAID DRUG REIMBURSEMENT POLICIES

The majority of existing brand name Medicaid drug payments is based on an "Average Wholesale Price" or "AWP" that is reported to the states by commercial drug compendia on a weekly or monthly basis. There is, however, no definition in statute or regulation as to what AWP means. Its value is determined by the compendia from manufacturer-reported information, either a "Wholesale Acquisition Cost" ("WAC"), a "Direct Price" or a "Suggested Wholesale Price" ("SWP"). The latter two terms also have no legal definition, and WAC had no definition until the Medicare Part D legislation introduced a definition of it as an "undiscounted list price" charged by manufacturers to wholesalers exclusive of any discounts, rebates or other reductions in payment. In general, the compendia will identify an AWP as either equivalent to the SWP (commonly reported for generics) or as a markup, currently 20%, to the WAC or Direct Price (generally used for brand name drugs.) Whether the WAC/Direct or SWP serves as the basis for AWP is a function of the historical practices of a manufacturer, but can also be affected by the manufacturer's decision to cease reporting one of these price types.

While most states employ the resulting AWPs as their reimbursement standard, some instead use WAC. However, state adjustments to both these price terms commonly result in their transformation into a similar reimbursement value. Additionally, most states apply Maximum Allowable Cost (MAC) limitations that set a single cap price on categories of generic drugs. The MACs are identified through a variety of means but can involve some form of a review of pharmacy invoice and payment information.

A movement to a non-AWP benchmark must start well before the anticipated target date. Any adjustment of a state's reimbursement formula or other material change to Medicaid program rules would require an amendment to the state Medicaid Plan and approval by the Centers for Medicare and Medicaid Services (CMS). Such CMS approvals of program changes can be involved processes that require a considerable amount of time. In addition to CMS requirements is the potential need for statutory or regulatory change (the use of "AWP as reported by the state's drug pricing compendium" is frequently embodied in controlling state law) at the state level. The states are thus obligated to begin to identify what pricing standard they will use as a replacement and to take the necessary political, procedural, information systems and practical steps to implement it. It is an effort that must commence virtually immediately.

CANDIDATES FOR REPLACEMENT OF AWP

The potential options for a new pricing standard are easily identified, and consist of a number of values already in existence in one form or another.

- **Wholesale Acquisition Cost** – While WACs are currently supplied by manufacturers there is a significant number of products for which it is not provided. It has much in common with AWP (in many instances it is currently the basis upon which AWP is calculated) and thereby presents some of the same challenges: WAC is a manufacturer-reported value that is not submitted directly to states; while currently defined[*], its definition as an undiscounted list price imparts an unclear correlation to true market prices. Used in conjunction with a well-designed Maximum Allowable Cost program that sets a cap on the pricing of generic drugs and their brand equivalent, WACs may serve as an interim pricing benchmark for brand name products until a better option is developed. However, there is no great reason for confidence that WAC will not become as subject to inflation over time, and regular surveys of actual acquisition costs would be necessary to validate WAC's correspondence to true market prices. WAC consequently does not appear to be a long-term solution.

- **Average Manufacturer Price** – AMP, a manufacturer-reported price defined in the Medicaid Rebate Statute as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade" has a distinct advantage as a pricing term: since AMP was devised to set the amount of the Medicaid Rebate that must be paid to states – with a higher AMP generating a higher rebate – it is a value that would never intentionally be overstated. This inherent self-limitation made it for a time the most likely candidate to replace AWP, and the AMPs previously reported only to CMS and maintained confidentially were to be publicly disclosed in December, 2007. Still, the use of AMP as a pricing benchmark raises some of the same concerns presented by WAC: it is a manufacturer-reported value that is not routinely validated by CMS or any other entity, and states would have to perform periodic acquisition cost surveys as validation. Furthermore, AMP is reported on a schedule such that the resulting value may not reflect current market pricing.

A concern that AMPs would not accurately represent pharmacy prices – revised defining regulations by CMS effective in October, 2007 required the inclusion of prices from a variety of non-retail pharmacy classes of trade, including hospitals, direct sales to physicians and patients, PBM mail order pharmacies and nominal sales – prompted pharmacy trade groups to seek declaratory relief in federal court and prevent publication of AMPs. Their application was granted and the resulting injunction still restrains any disclosure of AMPs nearly two years after it was initially granted. There is consequently no way of knowing now whether the defining regulations will be redrafted or what the

[*] "The term `wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." 42 USC 1395w-3a

final AMP will represent. More importantly, AMPs are not currently available and this price type therefore cannot be considered a viable option.

- **Average Sale Price** – Average Sale Prices, defined simply as the "sales to all US purchasers during the calendar quarter divided by total number of units sold"[*] are reported to CMS by manufacturers and used as the basis for Medicare reimbursement. Though ASP-based reimbursement prices are published at the aggregate level for categories of equivalent drugs, the ASPs for individual NDCs[**] are by law kept confidential, and thus without Congressional action are not accessible to the states. Further, ASPs only are calculated for Medicare Part B drugs, mostly injectable or inhalant products, and thereby provide little information for the majority of oral drugs most commonly dispensed by pharmacies. Like the AMP, ASPs are reported by manufacturers; however, they lack the relation to Medicaid rebates that provided the internal disincentive to inflation that exists with AMP. Moreover, neither AMP nor ASP provides much of an opportunity for states to conduct any meaningful review of the reported values, and the reliability of these prices would ultimately have to be taken on faith. Also, ASPs are reported only quarterly, raising the prospect of a substantial time lag before market price changes would be reflected in reimbursement. Finally, comparisons of ASPs to current AWPs show an extremely wide variation in the differential, making any formulaic conversion from AWP to ASP difficult to construct. For all these reasons, there is little basis for belief that ASP can be an effective replacement for AWP.

- **Maximum Allowable Cost** – As already indicated, MACs can and do serve as a cap on excessive reimbursement for generic products, and the concept of setting a single price for a group of generic equivalent products has merit. However, the calculation of a useful MAC value itself requires some valid benchmark. For instance, Federal Upper Limit prices, which have been historically set at 150% of the lowest published price (usually WAC) of the drugs in the same category, are routinely much higher than state MACs identified through a survey of in-state pharmacies. In simple terms, a MAC can only be as good as the data upon which it is determined and the frequency with which it is updated. MACs will remain an effective element of a comprehensive pricing policy, but the decision to deploy them does not eliminate the need to find accurate fundamental data on which to base them.

- **The best price charged to any insurer** – What has colloquially been referred to as a "most favored nation" policy, the requirement that pharmacies bill Medicaid the lowest amount they accept from any payor, has been implemented only by a few states and then only in limited circumstances. In principle it would operate to reduce Medicaid reimbursement to a minimum, but practically speaking compliance with this policy would be impossible to audit and rely solely on the data input at the pharmacy point of sale: the

[*] 42 USCS § 1395w-3a. Certain types of sales are exempt from inclusion in this calculation, including those at "best" or "nominal" prices.

[**] Since retail pharmacy claims are adjudicated and paid differentially for each NDC, a specific price must be identified at the NDC level.

substantial variance from provider to provider would eliminate the prospect of a standard, statewide price that could be deployed in a state's MMIS system. Reimbursement would obviously vary between pharmacies, arguably inequitably, and there would consequently be no pricing benchmark, national or otherwise. Like a MAC, a "most favored nation" requirement may be a component of a drug pricing policy but it cannot reasonably by itself be that policy.

- **Average acquisition cost ("AAC")** – A relationship of a reimbursement model to true average acquisition costs most literally complies with the Medicaid statute requirement of "estimated acquisition costs" and thereby would present the most defensible alternative pricing standard.[*] Gathered broadly enough, AAC data would be resistant to individual efforts to manipulate it, since any single price report would have only a minimal effect when included in a large array. Also, if gathered by the states, or the states' agents, there could be a sanction, implicit or explicit, for fraudulent reporting. Moreover, the use of an average price, rather than actual cost, as the benchmark would encourage providers to seek better prices and thereby exert downward economic pressure on the standard. Still, there would be considerable effort involved in the implementation of an acquisition cost benchmark, including the development of a precise definition of the information to be reported, the process for data acquisition and the identification of the reporting entity.[**] Particularly if a national price was the object, individual state efforts would have to be coordinated, or ideally, a federal definition and standard established, to avoid the prospect of multiple definitions and consequent confusion and inconsistency. While contemporary information technology resources would be able to handle the technical requirements of data intake, analysis and production relatively easily, there is no existing comprehensive average acquisition cost database and its creation can only occur through legislative and administrative change at both the state and federal levels. This option therefore has promise, but would require a significant political commitment to realize it.

CHALLENGES TO THE ADOPTION OF A NEW PRICING MODEL

The foreseeable obstacles in the replacement of AWP include definition, implementation, and approval challenges.

Benchmark Definition Challenges

- **Benchmark definition –** Whatever standard is chosen, the initial effort must be to provide a thorough and precise definition. While this may appear obvious, the number of factors that will need to be included in the definition process, beyond what the price term means and how it is to be calculated, may not be immediately evident. Will there be

[*] A recurring concern of pharmacy groups regarding the use of such price terms as AMP or ASP is that they bear no relationship to the prices pharmacies are actually paying. An acquisition cost calculated, for instance, from pharmacy invoices, successfully responds to this concern, and with its close adherence to the "estimated acquisition cost" requirement would be difficult to challenge legally.

[**] As will be discussed in more detail below, the Working Group considered the prospect of requiring reporting from pharmacies and wholesalers as well as the prospect of direct manufacturer reporting.

different data gathering techniques for different classes of trade, *e.g.*, independent pharmacy vs. chain pharmacy or mail order vs. specialty pharmacy? Will a single benchmark be adjusted for different classes in the payment process, or will there be no differential reimbursement schedule? Will there be state-specific prices, a California acquisition cost and a different Rhode Island acquisition cost, or will there be a single national price and, if the latter, how will a unitary definition and information gathering system be achieved? What will be the reporting frequency? What will be the relevant time period? What provisions will be made for outlier drugs for which the benchmark is temporarily unavailable? To be sure there are answers for all these questions, but the states must work through them, ideally in a consistent and coordinated fashion.

- **The time period to be used with reported data** – The question of timeliness will also have to be resolved in the identification of a new price type. At one end is the schedule on which data will be converted to a reimbursement price. Concerns have been raised that quarterly reporting is inadequately sensitive to market changes in pricing, so monthly or weekly updates will provide a more accurate standing. (With existing compendia routinely reporting weekly and even daily price changes, this solution is altogether feasible.) At the other end is the determination of the window of time to be employed in selecting the data that will generate the benchmark price. A manufacturer-reported value could be, and currently is, limited to the most recent price change, but wholesaler or pharmacy data would require a judgment as to how many transactions were to be encompassed by the price analysis – the last week's, month's or quarter's prices? Likewise, the question of the time lag between price changes and their appearance in the reviewed data would have to be addressed.

- **Customization or stratification of benchmark prices –** States would determine independently how any new pricing standard would translate to a payment, *i.e.*, whether the alternative price itself or a version modified with a multiplier or reducer was used as the ingredient cost reimbursement. Independently of that question, states would have the option of reimbursing differentially based upon, *e.g.*, regional considerations (urban vs. rural locations,) pharmacy business models (independents vs. chains vs. mail order) or any other factors deemed relevant. Implementation of any such considerations once decided would not be expected to present any difficulties in the data gathering and calculation process.

Implementation Challenges

- **Data acquisition –** The question of where the underlying data for a new benchmark will be gathered has already been noted above, and five potential avenues for obtaining drug pricing data can be identified:

    - Manufacturers could produce their prices to classes of trade relevant to the setting of pharmacy reimbursement rates – sales directly to pharmacies or to wholesalers that sell to pharmacies – in a slight adaptation of the AMP definition. In the absence of direct reporting to states the reliability of the standard would be questionable. In addition, manufacturers would likely

resist the potential liability attendant to the submission of such data. Also, it must be noted that the reporting of price data by manufacturers has proved problematic. While Texas, the only state that currently imposes such an obligation, has an outstanding record in its litigation of numerous false claims cases with manufacturers over price reporting, the very existence of such cases suggests that direct reporting has not served as a meaningful deterrent.

- Data could be obtained from major wholesalers. This would be a more manageable task in that the number of entities to be surveyed would be limited. However, the submission and collection would involve a large volume of data and may be viewed by submitters as unduly burdensome.. Furthermore, wholesaler data may be incomplete if it does not reflect discounts and rebates between manufacturers and certain pharmacy purchasers. Still, if the obligation can be imposed, the prospect of obtaining electronic files of sales invoices net of discounts would greatly facilitate the calculation of a national benchmark tethered to actual market prices.

- The federal government could execute a contract with a vendor to obtain national sales data from the major wholesalers. This would be similar to the contract CMS executed with IMS Government Solutions for the collection of retail drug price data pursuant to federal statutory requirements.[*] Plainly, a single federal requirement would be more cost-effective and administratively efficient than a parallel effort by fifty states, and may even have application in the identification of Medicare Part D or other federal program drug pricing.

- Pharmacy providers participating in any federally insured healthcare program could be required to report their acquisition costs. This could be accomplished universally through the inclusion of unit acquisition costs on Medicaid claims or selectively, through a survey or targeted pool of reporting entities. Pharmacies would also likely be opposed to the additional obligation of price reporting and in some instances there may be even be a question as to what their ultimate price actually is: given discounts that may relate to future events or sales targets, the price a pharmacy pays now may be reduced by later rebates, complicating the determination of what should be reported as a drug's "acquisition cost." Similarly, prices paid by pharmacies that negotiate prices directly with drug manufacturers and operate their own independent distribution centers may require additional analysis. On the other hand, as providers enrolled in state Medicaid programs, pharmacies are far more within the states' existing authority than wholesalers or manufacturers, and the concept of cost reporting has already been imposed within Medicaid for, *e.g.*, hospitals or durable medical equipment providers. Post-transaction

[*] 42 USCS § 1396r-8(f)

rebates or discounts could be reported annually, to test the degree to which a state's reimbursement formula was approximating true acquisition costs, or could be incorporated into reported prices based on good faith estimates of customary rebate recoveries. Depending on the structure of the data gathering process – whether reported to the state or to state contractors or consultants – the collection of pharmacy data could involve significant or relatively minimal administrative responsibilities for single state agencies. It is worth reiterating, however, that some states currently do conduct surveys of pharmacy costs on a monthly basis through a private consultant for the purpose of setting MAC prices.

- A final option would be to obtain data from the commercial electronic pharmacy switches that currently route billions of pharmacy claims from providers to appropriate payors. This prospect is appealing in that it could potentially be used to collect information from all sources regardless of government or private payor status. To be sure, for this to occur, all billing pharmacies would have to be required, legally or by contract, to identify their acquisition costs on the claims submitted through the switches. This alternative would also, as with wholesalers, require the cooperation of the switches, either through their compensation or the imposition of a legal obligation. Additionally, there would be a need for a significant overhaul to most state MMIS systems, as well as to those systems of commercial payor and pharmacies.

As the foregoing discussion indicates, if the states are to get better information they will have to require someone to provide it, whether to them or their agent, and it appears unavoidable that legislative action will be necessary to require that production. Also, whether that legislation is state or federal, or both, and who will have the responsibility for gathering, collating and reporting the data are major decisions that must be made in any acquisition cost based system. One basis discussed by the Working Group for the imposition of such a reporting requirement was the states' authority to regulate entities doing business within their borders, though there may be limits to which that rationale can be extended, particularly if there are penalties for inaccurate reporting. Clearly, a necessary element to any new pricing model will be acceptance and cooperation by affected stakeholders – both providers and price reporters – and a solution will have to involve navigation among an array of competing interests.

- **Pricing confidentiality –** A traditional impediment to any form of price acquisition has been the concern by price reporters that what they charge or pay is proprietary business information that should not be made public. Commercial advantages or skillful negotiation, it is argued, would be undermined if what any purchaser had been able to obtain as terms became known to every other purchaser. An immediate response to this perception would be to ensure that no *individual* purchaser's price was published, but only the average or median value of *all* purchasers' prices. While there may still be an argument that average/median price data would impair normal commerce – if the average became known every reasonable purchaser would seek below-average pricing – but the

existence of information about the most discounted prices in other business environments, *e.g.*, in internet sales, has not proven problematic. Also, as previously noted, there is existing precedent within Medicaid program rules for the requirement that providers identify their costs in the process of submitting claims.

- **Susceptibility of pricing information to review and potential for abuse –** A state reporting requirement would render the information submitted subject to audit, but the resource commitment necessary to conduct such audits would vary not only with the resources available to a state but also with the reporting entity selected. A review of manufacturer pricing, for instance, would be extremely time-consuming and involve analysis of large volumes of data and assessments as to what sales to which purchasers should be included in the determination of a benchmark price.[*]

Wholesalers and pharmacy purchasers, on the other hand, present a more favorable prospect. Since in both instances auditors would have the ability to compare data submitted by different entities for the same product, one could compare the pricing reported by Wholesaler A to that of Wholesaler B, or Pharmacy One's data to Pharmacy Two's, in a way that is not available when pricing is provided only by the manufacturer of a product. In principle, too, the review of sample invoices from a wholesaler or pharmacy is more feasible than an audit of a manufacturer's total sales. Similarly, the likelihood of intentional misreporting differs depending on the reporter. In a situation where manufacturers have the ability to define the reimbursement price to be paid by insurers, there can be an incentive to increase that price in order to induce purchasers to select particular products and increase market share. A soundly designed replacement benchmark would avoid creating such opportunities wherever possible. It might be perceived that pharmacies would benefit from reporting higher prices. However, if a large enough array of reporters existed and the average or median were used, no one individual report would theoretically affect the resulting price. A pharmacy falsely reporting an amount of $2 for a drug when all other pharmacies truthfully reported $1 would move the mean very little and may not move the median at all. To be sure, if many individuals or large-volume purchasers reported inflated values, average acquisition costs would be skewed. Therefore, explicit definition of terms, protection against outliers, and the prospect of potential sanctions for false reporting will always be a necessary component of a sound pricing model.

- **Administrative and data processing issues** – The task of assembling, sorting and generating desired price data would present a substantial task for any state, and is not a practical option. Existing activity by commercial compendia or private consultants will therefore likely continue, and current information processing capabilities are able to address even a large volume of drug data, once it has been acquired. Calculation of the desired value from that data, whether through a simple mean or median or an algorithm that excluded outlier prices and focused on a more limited data corridor, would be a straightforward programmatic operation. The acquisition process could be constructed in one of two ways: prices could be reported directly to the states and thence to its

[*] The AWP litigations undertaken by the states have demonstrated that substantial time and skilled audit staff are required to assess pricing for even a single manufacturer.

contractors or agents; alternatively, prices could be reported directly to such contractors and agents. Which data acquisition process is used will affect the administrative efforts necessary at the state level. It must be expected that any change in the reimbursement benchmark used for drug pricing will require some changes to existing IT systems, not only by states and their Medicaid Management Information Systems, but potentially at the provider or vendor level.

Federal Approval Challenges

- **Approval by CMS of changes to state reimbursement policies –** One of the more prominent concerns expressed by the Working Group was the recognition that any change to state Medicaid program rules will require CMS approval of State Plan Amendments. Given the time constraints that have been repeatedly expressed in this report, there is apprehension that the rate-limiting step in any pricing reform may be CMS review and endorsement. The Working Group consequently believes that it is essential that CMS be apprised of the potential range of state efforts and the need for quick action, and that insofar as possible there should be an integrated plan of action by state and federal authorities. Recognizing that CMS may be limited in its ability to confer approval in advance of state proposals, the Working Group still believes that significant and ongoing communications and coordination between all governmental authorities with a stake in Medicaid is fundamentally necessary to accomplish the shift to a new pricing standard.

CONCLUSIONS AND RECOMMENDATIONS

At this point and on the basis of current information, the Working Group can merely identify the pertinent issues that must be resolved in searching for a new drug pricing benchmark and provide a brief outline of potential solutions. Critical stakeholders – Medicaid programs, state legislatures, CMS, manufacturers, sellers and purchasers of drugs – will all be profoundly affected by any resolution, and anticipating how the interactions of these forces will play out, in a political environment where health care expenditures are at the top of the national agenda, is difficult to do with any confidence. Nonetheless, the fact that AWP will cease to be reported within two years, already a minimal time frame, must outweigh the intimidating scope of the task. The Working Group consequently offers the following conclusions and recommendations in the interest of beginning the process that will lead to a post-AWP reimbursement standard. Reimbursement for prescriptions under state Medicaid programs is calculated based on an estimated acquisition cost plus a reasonable dispensing fee. This paper addresses the estimated acquisition cost component of pharmacy reimbursement.

I. Establishment of a single national benchmark for pharmacy reimbursement based on actual acquisition cost data

- **A unitary benchmark reduces the likelihood of confusion, minimizes the burden on reporting entities, permits useful comparison and**

promotes national harmonization initiatives – A variety of replacements for AWP plainly runs the risk of causing marketplace inconsistency, if not chaos, and is directly counter to the national recognition that inconsistent standards in the provision and payment of healthcare are inefficient and wasteful. A single national standard will better serve the long term interests of both pharmacies and payors, will result in greater consistency in reimbursement and will support the efforts currently under way to reduce the inefficiency and waste in incompatible health care information technology.

- **A price benchmark based on average acquisition cost most clearly fulfills legal and practical requirements and has great potential, but will require resolution of questions involving its definition, source and implementation –** In outline the notion of basing reimbursement on what pharmacies ultimately pay not only complies with federal law but, if supplemented by a reasonable dispensing fee, is a demonstrably equitable and legally defensible standard. To arrive at it, however, there must be some form of mandatory price disclosure, both the nature of the reported value and the reporting entities will have to be determined and there must be a design for the administrative process of accumulating, analyzing and reporting data. Ideally, such efforts would be coordinated between groups of states if not all states and involve support and coordination from CMS.

- **WAC accompanied by a well-designed MAC program may provide an interim alternative but it should only be viewed as a temporary solution –** WACs are expected to be available for the majority of drugs when AWPs disappear, and a MAC cap on pricing derived from market price information can reduce its variability, but WAC cannot be seen as an easily sustainable solution. Its status as a manufacturer-reported value renders it practically impossible to audit, its definition as an "undiscounted list price" raises questions as to its correlation to actual market price, and there is concern that it could be subject to inflationary factors, thereby necessitating continual validation through regular acquisition cost surveys. Additionally, even use as an interim benchmark would require a State Plan Amendment for AWP states, meaning that two applications would ultimately be necessary to reach a final replacement price.

II. Efforts must begin now to establish the new benchmark, overcome resistance, and implement change

- **Action must begin immediately –** At the risk of reiterating the point just made, states are obliged to begin *now* to establish the process of conversion to a new benchmark. The exigency of this situation must be

emphasized to the administrative, legislative and regulatory authorities whose participation is required, and every available means of accelerating progress should be employed. All stakeholders need to meet internally and collectively, CMS must make the most of its opportunity to play a constructive role in a transition, and whatever support or information needed by political authorities has to be made available to them, all of this on a timetable commencing today.

- **There will likely be resistance to change that must be overcome if a new benchmark is to be developed –** As the foregoing discussion has repeatedly shown, there is no magic solution – no new price type will meet with universal acclaim and resolve all dilemmas. Some stakeholders will be affected adversely; indeed, inherent in the notion of a more efficient pricing process is the fact that those interests benefiting from inefficiency or pricing opacity will lose that advantage. Creation of a successor standard will therefore necessarily involve negotiation and compromise, but will also require the political will to implement a well-designed program. Formation of national coalition of stakeholders is a reasonable first step toward identifying stakeholder challenges and working toward compromise.

- **States must act in their own interest to work with all stakeholders to design a new drug price benchmark, and early adopters are likely to set the market standard –** Some interested party will endorse and seek to implement a replacement for AWP and whoever achieves that end first has a substantial opportunity to name the new price. A failure to act and act quickly, must therefore be regarded as an abdication of responsibility. All stakeholders should work together, transparently, and timely to determine the best course of action for all parties involved.

It is the hope of the Working Group that this report can constitute at least a first step in the process of creating a new drug price standard, and can help motivate affected stakeholders to begin to address the relevant questions. We intend to continue in our efforts to identify problems, solutions and opportunities related to the end of AWP, and we look forward to the engaged discussion of these issues that we anticipate will occupy with increasing urgency.