



American Pharmacists Association

Improving medication use. Advancing patient care.

October 1, 2004

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

RE: CMS-4068-P

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule implementing the Medicare prescription drug benefit. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The proposed rule establishes a Medicare prescription drug benefit as mandated by Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act). The Act is the most significant change to the Medicare program since its inception, and APhA recognizes the Administration and Congress for their efforts to provide prescription drug coverage for our nation's Medicare beneficiaries. Prescription drugs play a vital role in our modern health care system; and the new drug benefit will help the millions of elderly and disabled without prescription drug coverage – approximately one-third of all Medicare beneficiaries¹ – access valuable medications.

Developing regulations to implement the prescription drug benefit, just one of the many provisions contained in the Act, is clearly an arduous task. APhA commends the Centers for Medicare and Medicaid Services (CMS) for its efforts to develop implementing regulations for a workable benefit within a condensed timeframe. APhA is pleased the regulations recognize the valuable role of the pharmacist and the benefit pharmacist services can have on patient outcomes. The proposed regulation takes a significant step toward ensuring that patients can access necessary medications, and also obtain the services to help them make the best use of those medications. However, there are several areas of the regulation as published in the August 3rd *Federal Register* that require further clarification and improvement to ensure that the drug benefit is implemented as effectively as possible. We offer the following comments on those areas.

¹ Fact Sheet: Medicare and Prescription Drugs. The Henry J. Kaiser Family Foundation. April 2003.

SUBPART A: GENERAL PROVISIONS

Anti-Kickback Provision

The preamble of the proposed regulation includes a discussion of financial relationships between prescription drug plan (PDP) sponsors, health care professionals, and pharmaceutical manufacturers. According to the preamble, the financial relationships between these entities must be carefully considered in order to ensure that they do not violate Federal anti-kickback law or the Stark statute. The preamble continues to state, “PDPs are not prevented from paying pharmacies, for instance, for medication therapy management, provided that the PDPs do not violate anti-kickback and physician self-referral law.”² APhA appreciates the inclusion of this example to affirm that plans may pay pharmacists or pharmacies for pharmacist-provided patient care services such as medication therapy management (MTM) services. It also serves as a caution to plans that the Agency may examine their financial relationships with downstream entities.

APhA recommends that the Agency apply special scrutiny to the financial relationship between plans and pharmacies in which the plan has a financial interest. For example, a plan may use lower co-pays and other incentives to drive beneficiaries to a pharmacy associated with the plan to obtain medications or MTM services. The plan may benefit financially from beneficiaries patronizing this pharmacy. This scenario may violate the anti-kickback statute and we request the Agency address this issue in the final regulation. We also request that the Agency clarify that pharmacist identification of targeted beneficiaries for MTM services is not a violation of the anti-kickback statute. Similar to a physician identifying the need for a patient to return for a follow-up visit to manage a health condition, pharmacists may identify patients who require MTM services to manage their medications and improve health outcomes. Neither of these scenarios constitutes an inappropriate financial relationship.

SUBPART B: ELIGIBILITY AND ENROLLMENT

Beneficiary Selection

The creation of a separate Medicare prescription drug benefit, the transformation from Medicare+Choice to Medicare Advantage plans, and changes to the availability of drug coverage through Medigap plans are all significant changes to the Medicare program. Beneficiaries will be faced with new options and new decisions to make regarding prescription drug coverage. Current experience with the Medicare-approved prescription drug discount card program has shown that beneficiaries may refrain from enrolling in a prescription drug program when faced with a number of confusing choices. Beneficiaries have experienced difficulty in evaluating and selecting a Medicare-approved prescription drug discount card program. APhA is concerned that beneficiaries may experience similar problems when selecting a prescription drug plan. Beneficiaries will likely turn to their pharmacist, as they have with the discount card program, for assistance in evaluating plans. In recognition that pharmacists can and will serve as a resource for Medicare beneficiaries, the Agency should partner with pharmacists to educate beneficiaries and field their questions. To do this, CMS should work with APhA and others to prepare pharmacists to play this important role. The Agency should also compensate pharmacists for these services. Payment for these services must come directly

² 69 FR at 46,637.

from CMS as we understand that plan sponsors are prohibited from compensating pharmacists for certain education and outreach services such as enrollment assistance.³

SUBPART C: BENEFITS AND BENEFICIARY PROTECTIONS

Covered Part D Drugs

The new prescription drug benefit will provide coverage for prescription drugs, biological products, certain vaccines, insulin, and medical supplies associated with the injection of insulin. The benefit will not, however, provide coverage for all medications. According to the proposed regulation, covered Part D drugs will not include drugs for anorexia, weight loss, or weight gain; fertility promotion; hair growth; symptomatic relief of cough and colds; prescription vitamins or minerals; nonprescription drugs; outpatient drugs for which the manufacturer requires tests or monitoring services that must be purchased exclusively from the manufacturer or its designee; barbiturates; benzodiazepines; or any drug covered by Medicare Part A or B. APhA understands that the list of drugs not covered under Part D mirrors the drug exclusion list, except for smoking cessation products, under the Medicaid program. However, APhA is concerned that by excluding certain drugs from Medicare Part D coverage, health care providers will be forced to alter how they treat their patients based on which medications are considered a covered drug. For example, many providers currently prescribe barbiturates or benzodiazepines to treat mental health conditions or provide sedation. Under the new Part D program, providers may stop prescribing barbiturates and benzodiazepines and switch their patients to another, perhaps less effective or contraindicated class of covered drug. Barbiturates and benzodiazepines should be removed from the list of covered drug exclusions. We suggest that CMS seek a statutory change to provide the Agency with the authority to revise the list of covered drug exclusions.

Drugs that are not included on the list of exclusions are generally eligible for covered drug status if they are “used for a medically accepted indication.” As referenced in the proposed rule, medically accepted indication is defined under the Social Security Act as a use for a covered drug that is approved under the Federal Food, Drug, and Cosmetic Act.⁴ APhA recommends that the Agency consider expanding the definition of “medically accepted indication” beyond FDA-approved indications to include uses recognized in official compendia or research. We also question how pharmacists will know if a medication has been prescribed for an FDA-approved use. Although such information about the intended use will improve medication use and is something APhA supports strongly, prescribers are not required to include the medication’s intended use or indication on the prescription and it is unfortunately not yet standard practice to include this important information. Pharmacists generally receive and prepare prescriptions for patients, and submit reimbursement claims to plan sponsors for the product, without this information. We are concerned that plans may expect pharmacists to enforce this coverage limitation or attempt to hold pharmacists financially responsible if the pharmacist provides a beneficiary with a covered drug, charges the beneficiary the specified co-pay, and later learns that the medication was prescribed for an off-label, and therefore not covered, use. To address this situation, and to ensure that pharmacists have access to the information necessary to best serve their patients, APhA urges the Agency to include a recommendation in the final rule that prescribers include the indication or intended use on each prescription. CMS must also clarify that plans cannot ask pharmacists to police compliance with this requirement.

³ Education and Outreach Arrangements Between Medicare-Endorsed Discount Drug Card Sponsors and Their Network Pharmacies Under the Anti-Kickback Statute. HHS Office of Inspector General. April 8, 2004.

⁴ 69 FR at 46,815. Section 423.100.

APhA also requests that the Agency clarify that plans are not prohibited from providing coverage of drugs included on the exclusions list. Based on our understanding of the proposed regulation, plans are not required to provide coverage for these products under the standard benefit, but may offer coverage for these products as part of an enhanced drug program. Allowing plans to provide coverage for these medications as part of an enhanced program should attract beneficiaries to the plan and would help ensure beneficiary access to necessary medications. We seek clarification that our interpretation of this provision of the proposed regulation is correct.

Standard Prescription Drug Coverage

The preamble of the proposed regulation contains a discussion of the AIDS Drug Assistance Program (ADAP) which helps low-income patients with HIV/AIDS acquire necessary medications. The Agency solicits comments on the ability of ADAP programs to participate with prescription drug plans and the coordination of ADAP and Medicare Part D benefits. We encourage the Agency to coordinate benefits for ADAP beneficiaries through prescription drug plans. Coordinating care through PDPs would benefit ADAPs and the Medicare beneficiaries they serve by giving them access to Medicare Part D benefits such as medication therapy management services. HIV/AIDS patients who receive medications through ADAPs have a critical need for MTM services. These patients have a chronic, long-term medical condition that generally coexists with other medical conditions and requires the use of multiple, complicated, high cost medications. MTM services would help ensure that ADAP patients are using these medications correctly and achieving optimal health outcomes. Because patients must be enrolled in a PDP or MA-PD to receive these plan-paid MTM benefits, we recommend that CMS encourage plans to coordinate their coverage with ADAP programs.

Negotiated Prices

Under the proposed rule, plans are required to offer beneficiaries “access to negotiated prices for covered Part D drugs included in the plan’s formulary.”⁵ APhA strongly supports this requirement. Requiring plans to negotiate with manufacturers for lower prices should result in lower co-payments for beneficiaries and lower overall drug costs for the Medicare program, and it is especially significant for beneficiaries who reach the initial coverage limit. However, APhA is concerned that the regulation fails to establish minimum requirements for the amount of the discount or price concession that the plan must pass on to beneficiaries. We are concerned with the lack of specificity in this requirement. There is no guaranteed minimum discount. The amount of the discount shared with beneficiaries can vary greatly from plan to plan and from product to product. Plans could arguably meet the requirement to offer access to negotiated prices by simply passing one cent of savings to enrollees.

To ensure that beneficiaries receive the bulk of the negotiated savings from the manufacturer, the final regulation should specify that a majority of the savings must be passed through to beneficiaries either directly or indirectly through pharmacies. We recommend that the Agency add a requirement to the regulation that a “substantial portion” of the manufacturer rebates or discounts be passed through to beneficiaries. The regulation should also provide a definition for “substantial portion” of at least 75 to 80%.

APhA is also concerned that the regulation is silent on how the negotiated discounts will move from the plan, to the pharmacy, and ultimately to the patient. The regulation requires plans to provide

⁵ 69 FR at 46,817. Section 423.104 (h).

beneficiaries with access to negotiated (lower) prices by negotiating price concessions. We expect that plans will obtain these price concessions from manufacturers and pharmacies. However, the regulation fails to explain how the price concessions will be passed through to the pharmacy.

Under the prescription drug benefit, plans will negotiate price concessions, establish a price for each of its covered drugs, and inform participating network pharmacies of the price they should charge beneficiaries. The price set by the plan is based on the price concessions obtained from the manufacturer and/or pharmacy. However, it is important to note that the pharmacy's cost to obtain and provide the product remains the same. The pharmacy must be reimbursed at least a portion of the difference between the pharmacy's usual and customary price and the price negotiated by the plan. This can be accomplished by requiring plans to provide a portion of the negotiated discounts from manufacturers to participating pharmacies to compensate them for providing the drug at a lower price. Under the proposed rule, plans are merely required to offer discounted prices on covered drugs; it does not require plans to use the negotiated discounts to reimburse pharmacies for offering drugs at lower prices. The final regulation must include language to ensure that the financial administration or adjudication process assures that pharmacies are adequately reimbursed for providing drugs at a lower price. The reimbursement must also be made to pharmacies in a timely manner – no later than 30 days from the date of claim submission.

APhA also requests that the Agency strengthen its reporting requirements for prescription drug plans. Under the proposed regulation, plans are required to disclose to CMS “data on aggregate negotiated price concessions obtained from manufacturers and passed through to beneficiaries, via pharmacies and other dispensers,” in the form of lower subsidies, or to beneficiaries as lower monthly premiums or lower drug prices.⁶ It is unclear at what level plans must report negotiated price concessions. Will plans have to disclose aggregate negotiated price concessions per drug or the aggregate price concessions overall? Plans should be required to disclose aggregate price concessions per drug by active ingredient and manufacturer. Requiring plans to disclose negotiated price concessions by product will provide CMS with the appropriate information to evaluate plan sponsors' ability to provide beneficiaries with negotiated prices on covered drugs. Plans should also be required to report to CMS the amount of the price concessions obtained from manufacturers versus pharmacies, and how much – the percentage – of the price concessions from both sources that are passed through to the beneficiaries.

Dispensing Fee

CMS does not provide a definition for the term “dispensing fee” in the proposed rule; instead CMS proposes three different options for the definition. Option one states: “The dispensing fee would only include activities related to the transfer of the possession of the drug from the pharmacy to the beneficiary including charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale.” This option is the most appropriate definition to describe general dispensing of a prescription drug product; however, APhA has several questions related to the scope of the definition. The definition limits the dispensing fee to the “transfer” of the product from the pharmacy to the beneficiary. It is unclear which pharmacist/pharmacy activities related to dispensing CMS intends to include in the term “transfer.”

⁶ 69 FR at 46,817. Section 423.104 (h)(3).

The preparation and dispensing of a drug product is a multi-step process that contains several different components that each add a cost to the process. For example, after the beneficiary presents a prescription at the pharmacy, the pharmacist processes the prescription (entering information into the pharmacy's computer system, correcting clinical conflicts, complying with third party payor requirements, resolving conflicts with pharmacy benefit managers, etc.), prepares the order (retrieving the drug, selecting/preparing the correct amount, preparing the label, etc.), and delivers or dispenses the product to the patient (transferring the product to the patient, preliminary counseling the of patient, handling the financial transaction, etc.).⁷ There are also indirect costs associated with the dispensing process such as overhead costs related to cost of operating (pharmacist salaries, rent, electricity, etc.). All of these activities must be considered when establishing a dispensing fee. If the Agency will not set a specific dispensing fee, we urge CMS to add a requirement to the final regulation that plans must consider all of the costs associated with the processing, preparation, and delivery of the prescription drug product, including basic professional services such as basic patient counseling and overhead costs.

APhA further requests that the Agency consider the use of a tiered dispensing fee based on the level of complexity associated with preparing the product for the beneficiary. The time, effort, and skill required to prepare a medication for delivery to the patient can vary greatly depending on the product and the route of administration. For example, many products can be prepared by selecting the correct product, selecting the appropriate number of tablets, depositing the tablets in a prescription vial, and applying the appropriate labeling. For these products a one-level dispensing fee may be appropriate. However, this dispensing fee may not be adequate for products with a higher level of clinical complexity. Products that have a higher level of clinical complexity require additional preparation and a higher level of service performed by the pharmacist. These services are based on the complexity of providing the medication to the patient and are different and separate from MTM services. The initial clinical review and assessment of the appropriateness of the medication that occurs at the time of dispensing may differ based on the complexity of the medication involved. For example, the anticoagulation medicine warfarin[®] requires greater care because of its complex therapeutic mechanism of action and the dangers associated with drug and food interactions. Injectable drugs such as Enbrel[®] or Lovenox[®] require extra time to prepare because of dosage calculations and counseling on proper administration and use of the product.

A one level dispensing fee may also be inadequate for other products that require additional preparation such as reconstitution or compounding. Reconstitution, while distinctly different from compounding, requires more time and effort than selecting and delivering a prepared solid dosage form product. Compounding a product for delivery to the patient requires additional time, effort, and resources that may include specialized equipment. The extra time, effort, and resources required should be recognized in the form of a higher dispensing fee. At a minimum, if option one is selected, the term "mixing drugs" within the proposed definition should be further defined. It is unclear if "mixing drugs" refers to reconstituting a drug product according to manufacturer directions or the compounding of a customized drug product. If the Agency forgoes the creation of a tiered dispensing fee, at a minimum, CMS should create a separate dispensing fee for pharmacy compounding.

⁷ Pharmacy Activity Cost and Productivity Study. Performed by Arthur Anderson LLP for the National Association of Chain Drug Stores Education Foundation. November 1999. Pg. 6.

APhA recommends that the Agency adopt option one, as amended, as the definition for non-home infusion therapy. If the Agency selects option one, CMS must also clarify that the second half of the definition, “would not include any activities beyond the point of sale,” is subject to vary narrow interpretation. We are concerned that plans could attempt to use the definition to prohibit pharmacists from charging non-targeted beneficiaries for medication therapy management services. Under the Act, plans are instructed to provide and pay for MTM services for targeted beneficiaries. However, other beneficiaries who do not meet the “targeted beneficiary” criteria may also need MTM services. Non-targeted beneficiaries should have the option to receive MTM and pay pharmacists directly for these services. CMS must prohibit plans from limiting pharmacist services beyond the point of sale.

APhA also requests that the Agency clarify specific terms within the definitions for option two and three. Options two and three provide definitions that are limited to dispensing related to home infusion therapy. Option two would include activities in option one as well as “amounts for any supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered.” It is unclear if the term “supplies and equipment” referenced in the definition includes payment for home infusion administration devices. Payment for the administration devices associated with a growing number of home infusion products should be included in the definition. Payment for the devices should not require a separate billing process.

Option three includes all of the activities in option two as well as “activities associated with ensuring proper ongoing administration of the drugs such as professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.” It is unclear why the definition includes the term “clinical” pharmacist. APhA recommends that the Agency delete the word “clinical” from proposed definition option three.

Pharmacy Access Standards

Congress included several provisions in the Act intended to preserve Medicare beneficiaries’ access to the pharmacist of their choice. APhA is pleased that both the Act and the proposed regulation prohibit plans from restricting beneficiaries to one type of pharmacies, such as mail service pharmacies. Allowing beneficiaries to utilize the pharmacist and pharmacy of their choice – whether it is a community or mail service pharmacy – is crucial to protect existing patient-pharmacist relationships. The patient-pharmacist relationship is an important link in ensuring appropriate and safe medication use.

We also appreciate the inclusion of the TRICARE Retail Pharmacy (TRRx) network access standard as one of the requirements that plans must meet in order to offer a prescription drug benefit. Under the pharmacy network access standard, plans must secure the participation of a sufficient number of community pharmacies in their pharmacy network. According to the report language accompanying the Act, Congress included the TRICARE pharmacy network access standard to ensure that beneficiaries have “convenient access...to a bricks and mortar pharmacy” in close proximity to their residence.⁸

While we commend Congress for the inclusion of the TRICARE requirement, we are disappointed with the Agency’s proposal to implement this provision in two areas: one, the Agency’s proposal to

⁸ Report Language. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pg. 64.

measure plan compliance and two, the use of “preferred pharmacies” in plan networks. The TRICARE standards require that 90% of beneficiaries in urban areas have access to a pharmacy within 2 miles, 90% of beneficiaries in suburban areas have access to a pharmacy within 5 miles, and 70% of beneficiaries in rural areas have access to a pharmacy within 15 miles. CMS has proposed measuring compliance with the TRICARE standard across the plan’s service area. Under the proposed rule, plans would only be required to meet the pharmacy access standard “on average” within each region in which they operate. Plans would not be measured for compliance with the access standard on the local level. APhA has significant concerns with this proposal.

The Agency’s proposal to allow plans to measure compliance “on average” within the region is concerning, because the size of the regions have not yet been defined and because “average” access does not help individual beneficiaries. A region could be as small as a single state or as large as several states or an entire section of the country. If CMS allows plans to measure compliance with the TRICARE requirement at the regional level, there is no guarantee that all beneficiaries will have access to a community pharmacy. Because plans would be allowed to average compliance with the access standard across urban, suburban, and rural areas, plans could be considered in compliance with the access standard requirement even though many beneficiaries may not have convenient access to a network pharmacy.

Plans should be required to meet the TRICARE requirements on all program levels – ensuring all beneficiaries, whether they reside in urban, suburban, or rural areas – direct interaction with a pharmacist. Requiring plans to meet the requirements on a local level will also provide plans an incentive to offer community pharmacies acceptable program contracts to gain their participation in the pharmacy network. Without such an incentive, plans may not even attempt to contract with community pharmacies in rural areas within the plan region, leaving those beneficiaries without access to their drug benefit or necessary MTM services. APhA urges CMS to measure plan compliance with the TRICARE pharmacy network access standard on the local level. At a minimum, plans should be required to meet the access standard in each state within the region in which the plan operates.

The Agency should also further expand upon the TRICARE requirement that pharmacies are located within a certain number of miles of the beneficiaries. Specifically, CMS should set a standard for how plans must measure the distance to pharmacies. As the proposed regulation is currently written, it appears that plans would be allowed to measure the geographic distance between beneficiaries and pharmacies. The geographic distance is not an accurate measure. For example, a beneficiary in a rural area could live 14 miles away from a participating pharmacy if the plan measures the geographic distance between the beneficiary and the pharmacy as a straight line. However, the actual travel distance, based on the availability of commercially traveled roads, may be substantially longer and fail to meet the access requirement of the TRICARE standards. CMS should require plans to measure the distance to pharmacies using commercially traveled roads.

To ensure that plans are meeting the pharmacy access standards, CMS should also require plans to demonstrate to the Agency that the plan has a sufficient number of community pharmacies in their network to meet or surpass the TRICARE standards. Plans should be required to provide documentation to the Agency that each pharmacy listed within the plan’s pharmacy network has in fact agreed to participate as a network pharmacy. Requiring plans to confirm pharmacies’ participation with CMS may eliminate some of the problems that occurred when plans “enrolled” pharmacies for the Medicare Prescription Drug Discount Card Program. APhA is aware of complaints from pharmacies

that were listed on the www.Medicare.gov website as participating pharmacies for a discount card program, although they had never agreed to participate in that discount card program. We are aware of at least one pharmacy listed that had ceased operating several years before the discount card program was released. Requiring plans to obtain written affirmation from pharmacies that they agree to participate in the network will allow CMS to accurately measure plans' compliance with the TRICARE pharmacy access standards, and will ensure that beneficiaries have accurate information when evaluating the participation of their pharmacy in the network of various plans.

We also request that the Agency address a related problem in the final regulation – the tying of pharmacy contracts. Based on our understanding of the proposed rule, it does not appear that plans are required to obtain a signed statement or contract from a pharmacy specifically stating the pharmacy's willingness to participate in the plan's Medicare prescription drug program. APhA is concerned that plans may rely on language in existing pharmacy contracts that would require the pharmacy's participation in the Medicare prescription drug program. Pharmacies should be asked to expressly agree to participate in the plan's pharmacy network for the Medicare benefit.

Pharmacists should be allowed to evaluate every plan contract that they are offered, and make the decision whether or not to participate independent of any other network or plan contracts. The final rule should prohibit plans from requiring pharmacies to participate in the plan's Medicare prescription drug program as a condition of participating in the plan's non-Medicare plans or networks. Plans must be required to offer separate contracts for the Medicare program, regardless of the pharmacy's participation in other networks of the sponsor. We request that the Agency eliminate the potential for the tying of these contracts.

APhA also requests that CMS provide additional insight into the availability of waivers for Medicare Advantage Prescription Drug Plans (MA-PDs). According to the proposed regulation, MA-PDs are eligible for a waiver of the TRICARE pharmacy access requirement if the plan has "comparable access." The regulation, however, fails to explain what constitutes comparable pharmacy access. MA-PDs should be required to meet the same access standards as PDPs.

On a related issue, the preamble to the proposed regulation includes a discussion of federally qualified health centers (FQHCs) and the need for beneficiaries that utilize FQHCs to maintain that access under the Medicare prescription drug benefit. APhA agrees with the Agency that low-income beneficiaries – especially in rural areas – should be able to continue to obtain their medications from FQHCs when enrolled in a Medicare prescription drug plan. While we do not believe that FQHC pharmacy services should be counted when plans assess whether they meet the TRICARE access standards because they are not accessible by the general population, plans should be required to include FQHCs in their pharmacy network. APhA recommends that CMS require plans to solicit all FQHCs within their region and enroll a proportionate number to ensure low-income beneficiaries convenient access to these services.

Any Willing Provider

The Act contains another requirement – the any willing provider provision – to ensure that beneficiaries are provided with easy accessibility to local pharmacies. The provision requires plans to permit any pharmacy willing to accept the plan's terms and conditions to participate in the plan's

pharmacy network. APhA appreciates the inclusion of this requirement in the Act; however, we are concerned that the Agency has dramatically weakened this requirement in the proposed regulation. Under the proposed regulation, plans would allow any pharmacy willing to contract with the plan to participate in the plan's pharmacy network, but plans would be allowed to make distinctions between the pharmacies in the plan's network designating pharmacies as "preferred" or "non-preferred." Plans could offer the traditional 25% co-pay at "non-preferred" pharmacies within the network, and reduced co-pays for beneficiaries who obtain their medications at "preferred" pharmacies.

APhA is extremely concerned with the Agency's flawed interpretation of the any willing provider requirement contained in the Act. Congress established explicit limits on the size of preferred pharmacy networks. The statute clearly states that "for covered Part D drugs dispensed through in-network pharmacies" plans may "reduce coinsurance or co-payments for Part D eligible individuals enrolled in the plan below the level otherwise required" [emphasis added].⁹ This provision provides plans with some flexibility in establishing cost-sharing requirements for beneficiaries. Plans can set beneficiary co-payments below the 25% standard for medications – a marketing tool that may help plans attract beneficiaries. However the language is explicit, plans may reduce the cost-sharing for pharmacies in the plan's network (the network meeting the TRICARE access standards). The Act does not suggest that plans can reduce co-payments for a subset of pharmacies within the plan's network, essentially creating a network within a network.

Allowing plans to create a preferred network within their overall pharmacy network clearly violates Congress' intent that plans provide beneficiaries convenient access to pharmacies that is "no less favorable...than the rules for convenient access...in the TRICARE Retail Pharmacy Program."¹⁰ To participate in the Department of Defense's (DoD) pharmacy network, plans must offer enrollees access to pharmacies that meets or exceeds the TRICARE access standards. All of the pharmacies in the DoD network offer uniform cost sharing. Pharmacies not in the DoD network have a different, higher cost-sharing requirement than in-network pharmacies. CMS' intention to allow plans to create a smaller network of preferred pharmacies with lower cost-sharing requirements is not consistent with the DoD's application of the TRICARE standards, and does not meet Congress' intent that plans "cannot create any pharmacy networks that are more restrictive than the TRICARE access standards."¹¹

Allowing plans to vary beneficiary cost-sharing between preferred and non-preferred pharmacies allows plans to drive beneficiaries to a particular pharmacy. Again, this is not what Congress intended when adding this provision to the Act. Congress added the any willing provider provision to ensure beneficiaries' access to the pharmacy of their choice. Congress wanted to prevent plans from using differences in cost as a method of steering beneficiaries to a particular pharmacy.¹² As currently written, the proposed regulation undermines Congress' efforts. Allowing plans to distinguish between preferred and non-preferred pharmacies would effect beneficiary access to the pharmacy of their choice and significantly disadvantage certain network pharmacies. It may also create a self-referral issue for plans that eliminate or significantly reduce co-payments for medications obtained through

⁹ Section 1860D-4. Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

¹⁰ Report Language. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pg. 25.

¹¹ Report Language. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pg. 25.

¹² Senator Enzi. Congressional Record S15743. November 24, 2003.

their affiliated pharmacies. APhA urges the Agency to remove its proposal to allow plans to distinguish between pharmacies within the plan's network from the final regulation.

APhA also recommends that CMS require plans to offer a standard contract to all pharmacies. The standard contract should be reviewed and approved by the Agency in advance of plan distribution to potential network pharmacies. Any adjustments to the terms of the contract should be made through an addendum to the contract. If the Agency allows plans to designate preferred and non-preferred pharmacies, plans should be required to state the amount of the non-preferred network pharmacy co-pay (which we expect would be the standard benefit co-pay of 25% or its actuarial equivalent) and the amount of the preferred pharmacy co-pay in the standard contract. Additionally, we insist that the Agency clarify that non-preferred pharmacies may not be counted when assessing whether the plan meets the pharmacy access standard requirement.

Level Playing Field

Under the Act, plans must allow beneficiaries to obtain their benefits at a network community pharmacy or a mail service pharmacy. This provision, similar to the pharmacy access standard and the any willing provider requirement, is designed to ensure that beneficiaries are able to access their benefit from the pharmacist and pharmacy of their choice. This requirement will allow beneficiaries to obtain benefits such as an extended 90-day supply of medications – a benefit that in the private market is typically only available through a mail service pharmacy – and medication therapy management services from a community pharmacy.

APhA appreciates and supports the level playing field requirement; however, we do have some concerns related to the additional costs plans may charge beneficiaries who obtain their benefits from a community pharmacy. It is our understanding that the price differential would be in the form of a higher co-payment. However, the proposed regulation does not provide adequate guidance on how the cost differential should be determined. The regulation also does not appear to impose a cap on the price difference the beneficiary is charged.

APhA is concerned that the Agency has provided plans with too much discretion in this area. It was Congress' intention that the difference in price be based solely on the additional cost of providing the service at a community pharmacy. When discussing the level playing field provision of the Act, Senator Grassley expressed his expectation that the "difference in charge be reasonable and based on the actual cost of providing the service in or through the setting in which it is provided" [emphasis added].¹³ This sentiment was echoed and expanded upon by Senator Enzi who stated that "any differences in charges between mail order and retail be reasonable differences based on the actual cost of delivering the services. I would be concerned if differences in charges were used as a method of steering seniors and the disabled to mail order pharmacies."¹⁴ Congress clearly wanted to prevent plans from charging beneficiaries a higher fee based on arbitrary factors and was concerned that plans would charge higher fees to drive beneficiaries to mail service pharmacies. Representative Crane instructed Department of Health & Human Services Secretary Thompson to address this concern when implementing this portion of the drug benefit:

¹³ Senator Grassley. Congressional Record S15743. November 24, 2003.

¹⁴ Senator Enzi. Congressional Record S15743. November 24, 2003.

I hope that when HHS implements the drug coverage portion of this law that you will work to make sure that drug plans do nothing to intentionally discourage seniors from choosing a 90-day supply of drugs from their local pharmacies. I am especially concerned that drug plans may attempt to steer seniors to their mail order businesses by requiring higher co-pays or other cost sharing just for choosing to obtain a 90-day supplement from this neighborhood pharmacy. That was not the intent of this Committee, and I urge you to be vigilant in preventing plans from doing this.¹⁵

APhA urges the Agency to follow Congressional intent and strengthen this provision of the regulation to ensure that beneficiaries are not charged unreasonable prices for continuing to use their community pharmacy. CMS should provide guidance on determining the cost differential in the final regulation. The Agency should specify that the price differential must be limited to the difference in providing the service, not the cost of the drug product. APhA also requests that the Agency clarify that any cost differential paid by the beneficiary applies towards the beneficiary's true out-of-pocket (TrOOP) expenditures, and that beneficiaries may access an extended supply of any amount, not just the 90-day supply referenced in the proposed regulation. We are concerned that plans could circumvent the level playing field requirement by prohibiting network pharmacies from providing other quantities such as a 95 or 100-day supply. The level playing field requirement must apply to all product quantities/days supply.

Formulary Requirements

Although the new Medicare prescription drug benefit is a national program, not all Medicare beneficiaries will have access to the same covered drugs. Under the Act, each plan is allowed to develop a formulary of the prescription drug products the plan will cover. There will not be a uniform national drug formulary that covers all Medicare beneficiaries – formularies will vary from plan to plan. However, plans using a drug formulary must meet general standards established by CMS.

The proposed regulation includes a requirement that plans provide coverage for at least two drugs within each therapeutic category and class of covered Part D drugs. APhA has been monitoring the development of the U.S. Pharmacopeia (USP) model formulary guidelines and has provided comments directly to USP on the identification of appropriate categories and classes. Rather than repeat all of our concerns here, we must take this opportunity to express our general concerns with the use of formularies in the Medicare program. APhA understands the economic considerations behind formularies; it would be difficult for plans to provide coverage for every prescription drug. However, we are concerned that the creation of a narrow formulary or a formulary with a very limited number of products will adversely affect beneficiaries' access to needed medications. The elderly and disabled are two of the most vulnerable patient populations and often have unique and critical medication needs. Because providers will be pressured to prescribe medications contained on a plan's formulary, there is the potential for significant switching of medications. Beneficiaries who are currently utilizing medications may find that their medication regimen is changed to comply with formulary requirements. Switching medications, especially after long-term use, can have detrimental effects on beneficiaries' health outcomes. APhA requests that CMS require plans to include a large number of pharmacologic classes on their formularies to ensure that beneficiaries have access to a wide range of medications.

¹⁵ Representative Crane. President's Fiscal Year 2005 Budget for the U.S. Department of Health & Human Services. Hearing before the Committee on Ways and Means. February 10, 2004.

APhA supports the requirement that plans that use a drug formulary must develop the formulary with the help of a pharmacy and therapeutic (P&T) committee. Under the proposed rule, the majority of the P&T committee members must be practicing physicians and/or pharmacists and at least one of each must be an expert in the care of elderly and disabled individuals. APhA strongly supports this requirement; practicing pharmacists and physicians work most closely with Medicare beneficiaries and are familiar with their medication needs. To ensure that the P&T committee has an appropriate mix of both pharmacists and physicians, APhA recommends that the Agency revise the requirement to state that the P&T committee must be comprised of an equal number of physicians and pharmacists. Requiring plans to have an equal number of these health care professionals will help create a more balanced P&T committee.

The proposed regulation also requires plans to establish an exceptions process through which beneficiaries can request coverage for a non-formulary medication. The Agency provides general guidance on the process plans must follow such as responding within 14 days of an exceptions request. APhA is concerned that plans have 14 days to respond to an exceptions request. Two weeks is too long for a patient in need of a medication for an acute condition such as an antibiotic or an analgesic. CMS should revise the guidelines to require plans to respond to appeal requests within 72 hours.

We are also concerned that plans appear to have leeway on the exact design of the exceptions process. APhA is concerned that by allowing plans so much flexibility in the design of the exceptions process, each plan will develop a process that operates differently. If this occurs, pharmacists, physicians, and other health care professionals will have to learn how to work with as many exceptions processes as there are plans. This will lead to confusion and an increased administrative burden for health care professionals. The Agency should establish standards for the exceptions process; the exceptions process should be the same across all plans. Providers should not have to learn a different process for each plan.

We also believe there is need for standardization in the notification process for formulary changes. Under the proposed regulation, plans must notify CMS, affected beneficiaries, authorized prescribers, pharmacists, and pharmacies of the change at least 30 days prior to the change taking effect. APhA appreciates the requirement that plans provide advance notice; however, as with the exceptions process, there needs to be some level of standardization for how the notice occurs. This is especially important for health care professionals who will be receiving notices of formulary changes from a multitude of plans. APhA requests that the Agency establish a standard process for providing formulary changes that plans are required to follow.

Standard ID Card

APhA strongly supports the requirement that plans issue beneficiaries a standard identification card. Currently more than 70% of prescriptions are paid for by one of many third party payors, each with its own unique benefits card. Dealing with the administrative burdens created by inconsistent and confusing prescription drug cards creates unnecessary barriers that affect pharmacists' ability to provide care to their patients. By requiring plans to use the APhA-stimulated and National Council for Prescription Drug Program's (NCPDP) endorsed Pharmacy ID Card Standard, every Medicare beneficiary will present an ID card at the pharmacy that contains the information required by the NCPDP standards displayed in the appropriate location on the card. This will benefit both pharmacists

and patients by decreasing stress and frustration; enhancing opportunities for patient interaction including medication therapy management services, counseling, and drug utilization review; and increasing convenience for the patient.

Out-of-Network Pharmacies

The proposed regulation includes special rules for beneficiary access to medications at out-of-network pharmacies. APhA understands the Agency's concern that beneficiaries have access to necessary medications when beneficiaries cannot reasonably obtain their medications at a network pharmacy. However, we are concerned that CMS' expectations for out-of-network pharmacies are unrealistic. Under the proposed rule, beneficiaries who obtain a medication from an out-of-network pharmacy are responsible for paying their deductible or co-payment and the difference between the pharmacy's usual and customary price and the plan's allowance for that medication. It is not clear how out-of-network pharmacies will know what to charge beneficiaries. If an out-of-network pharmacy cannot file an electronic claim with the plan, the pharmacy will not have access to necessary plan or beneficiary information. In order for an out-of-network pharmacy to determine the correct amount to charge the beneficiary, the pharmacy must know if the beneficiary has met his/her deductible, if the beneficiary has reached the coverage limit of \$2,250 (the "doughnut hole") and is not eligible for drug coverage, or if the beneficiary has reached the catastrophic coverage limit of \$3,600 and is eligible for reduced co-insurance, as well as the plan's allowance for the medication, the co-payment amount required by the plan, and if the medication is on the plan's formulary. Because out-of-network pharmacies will not have a contract with the plan, it is not clear if these pharmacies will have a way to access or obtain this information. Out-of-network pharmacies will also have no means to recoup payment from the plan. APhA asks the Agency to require plans to accept claims from out-of-network pharmacies to address this issue.

If plans are not required to accept online claims from out-of-network pharmacies, APhA requests that CMS revise the out-of-network pharmacy provision in the final regulation. If a beneficiary must use an out-of-network pharmacy and the pharmacy is unable to access the plan information, the pharmacy is limited in their ability to serve the beneficiary under the terms of the beneficiary's prescription drug plan. The pharmacy can only charge the beneficiary its usual and customary price for the medication. The beneficiary will then have the option of seeking appropriate reimbursement directly from the plan.

Dissemination of Plan Information

According to the preamble of the proposed regulation, CMS is considering using the Agency's Medicare website to post information on the various prescription drug plans. APhA supports the use of the Medicare website as an educational tool. To help beneficiaries evaluate plans, we recommend that the website include information not only on the plans available in each region and the negotiated prices offered by each, but also the pharmacies within the plan's network and information on the medication therapy management services offered – including who is eligible for them – among other plan benefits. We agree with CMS Administrator McClellan that beneficiaries will want to evaluate the prescription drug benefit offered by plans by something other than just the drug costs.

After beneficiaries have selected and enrolled in a plan, the proposed regulation requires plans to provide a statement of benefits information to beneficiaries on a monthly basis. The preamble of the proposed regulation suggests that the explanation of benefits could be provided to beneficiaries at the

pharmacy.¹⁶ APhA strongly objects to this suggestion. Pharmacies should not be responsible for disseminating plan information to beneficiaries. Pharmacies are also not equipped to provide this information. For pharmacists to provide this information, pharmacy software would have to be modified, additional printing equipment and paper supplies would have to be obtained, and pharmacies would have to dedicate additional staff resources and time to generate and provide these reports. Plans would also have to provide pharmacies with the information to include in the reports; pharmacies do not normally have access to all of the required information which includes the item for which the plan paid and the amount of the payment, a notice of the beneficiary's right to obtain an itemized statement, the year-to-date total amount of benefits provided, the year-to-date total of incurred costs, and any applicable formulary changes. APhA insists that the Agency clarify that plans cannot require pharmacies to distribute the statement of benefits on their behalf.

Informing Beneficiaries About Price Differentials

Under the proposed rule, plans must ensure that pharmacists inform beneficiaries of any price differential between a covered Part D drug and the lowest priced generic version of that drug available under the plan at the pharmacy. APhA supports this requirement. Generic medications are an appropriate method of increasing access to necessary medications and reducing costs to beneficiaries, plans, and the Medicare program. As the regulation is currently written, community pharmacies must provide this information to the beneficiary at the time of purchase while mail service pharmacies can provide this information to beneficiaries at the time of delivery. To provide beneficiaries the opportunity to make use of this information and opt for a less expensive generic medication, mail service pharmacies should be required to inform beneficiaries of the availability of a lower price generic before dispensing the higher-priced medication.

SUBPART D: COST CONTROL & QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG BENEFIT PLANS

Drug Utilization Management

Plans are required to establish a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate, such as the use of different dispensing fees to encourage the use of multiple source drugs, prior authorization, step therapy, tiered cost-sharing, and other utilization tools. APhA is generally supportive of this requirement.

Drug utilization review (DUR) programs are in common use today – state Medicaid agencies require DUR programs and most health plans use a combination of retrospective and prospective DUR. Retrospective DUR, which involves a periodic examination of claims information, is useful in identifying fraud, abuse, and medication overuse, and in identifying inappropriate or medically unnecessary care. CMS should require PDP and MA-PD plans to operate a retrospective DUR program. “Medication therapy can be the most cost-effective provision of a healthcare benefit by preventing illness, controlling progression of a disease, and by enhancing the quality of life. However, if the medication is ineffective, abused, redundant, causes an adverse event, or if the therapy is inappropriate, the money spent on this therapy is wasted and additional treatment costs can be incurred.”¹⁷ Retrospective DUR programs can help the Agency and plans identify if beneficiaries are

¹⁶ 69 FR at 46,665.

¹⁷ Medicare Prescription Drug, Improvement and Modernization Act (MMA) and Retrospective Drug Utilization Review. American Drug Utilization Review Society. April 2004.

receiving therapeutically appropriate and cost-effective medication therapy. Retrospective DUR conducted at a state level by Quality Improvement Organizations (QIOs) or other organizations may also be appropriate.

Prospective DUR is useful in identifying the potential for adverse drug interactions, allergy interactions, therapeutic duplication, and drug-disease interactions. Prospective DUR is performed by pharmacists at the point-of-sale, often in conjunction with the plan's adjudication process. When a pharmacist prepares a prescription, the pharmacist performs a prospective review of the patient's medications regimen to prevent drug-related problems that, if uncorrected, might lead to adverse effects or failure to achieve treatment goals.¹⁸ "In performing prospective DUR, most pharmacists are assisted by DUR software applications that are resident on their pharmacies' computer systems."¹⁹ Pharmacists also receive DUR information from plans as part of the claims adjudication process. Plans measure the claim information against pre-determined standards and medication claims already on file and frequently send electronic messages based on this examination back to the pharmacist.²⁰

Unfortunately, the number of messages pharmacists receive from plans, the wide breadth of activities the messages are related to, and the vague nature of the messages, can make the DUR alerts generated by these clinical support tools more of hindrance than a help. A study of pharmacy activities found that pharmacists spend, on average, 32% of their time on prescription processing activities such as complying with third party requirements, resolving conflicts with pharmacy benefit managers (PBMs), and addressing DUR alerts. Other pharmacy personnel spend approximately 24% of their time handling prescription processing issues.²¹ This is valuable time that pharmacists could spend on patient care activities such as providing patient counseling and medication therapy management services.

Standardization among plan's DUR programs would increase the programs' effectiveness and decrease the administrative burden current DUR programs place on pharmacists. APhA recommends that CMS establish standards for DUR programs that plans must follow when providing a Medicare prescription drug benefit. The standards should address prior authorization and set one method that all plans must use to conduct prior authorization activities. The standards should also address electronic messaging to ensure that electronic DUR messages are optimally developed and transmitted. Pharmacists must be able to understand why the DUR message was sent, what the message means, and what action should be taken based upon that message. We recommend that the Agency consider the "Guiding Principles for Effective Electronic Messaging" that were developed by a group of pharmacy and insurance associations ([See Attachment A](#)).

CMS should also require plans to inform both health care providers and beneficiaries of the plan's DUR program requirements. Advance knowledge of the plan's DUR program requirements will help enable providers and beneficiaries to work within those requirements and obtain necessary medications without unnecessary delays in patient care. If the Agency adopts APhA's recommendation to establish

¹⁸ Chrischilles, Elizabeth, et al. The Role of Pharmacy Computer Systems in Preventing Medication Errors. *Journal of the American Pharmaceutical Association*. Vol. 42, No. 3. Pg. 439.

¹⁹ Chrischilles, Elizabeth, et al. Ibid.

²⁰ Fulda, Thomas, et al. Medicaid Drug Utilization Review Annual Reports for Federal Fiscal Year 1999: Looking Back to Move Forward. *Journal of the American Pharmaceutical Association*. Vol. 44, No. 1. Pg. 71.

²¹ Pharmacy Activity Cost and Productivity Study. Performed by Arthur Anderson LLP for the National Association of Chain Drug Stores Education Foundation. November 1999.

standards for DUR programs, the consistency across all plans will make learning different requirements for each plan unnecessary.

APhA also offers our support for the Agency's proposal to place DUR programs under the control of the pharmacy and therapeutic committee. We also support efforts to encourage the use of multiple source drugs such as providing a higher dispensing fee for these products.

Quality Assurance

Under the proposed regulation, plans would be required to provide a quality assurance (QA) program. According to the regulation, the program must include measures and systems to reduce medication errors, reduce adverse drug interactions, and improve medication use, as well as requirements for DUR, patient counseling, and patient information record keeping. APhA supports this requirement and the recommended program elements – electronic prescribing, educational interventions, bar codes, and adverse event reporting – the Agency lists in the proposed rule. Quality assurance is essential to pharmacy practice and to drug benefit programs in general.

We are concerned, however, that CMS is considering using medication error rates as a stand alone measure of quality. The preamble includes a discussion on medication errors, how the Agency may require quality reporting to include error rates in the future, and how this information could be used by CMS and beneficiaries to evaluate plans. We do not believe medication error rates should be used to compare plans. Quality should not be linked to error rates because simply examining the number of medication errors may be misleading. Proper evaluation of medication errors requires additional information such as the situation in which the error occurred, where the error occurred in the process, the type of error, whether the error reached the patient, the result of the error, and a process for ensuring complete reporting. It does not appear that plans would be required or even able to provide this type of detailed information to CMS. This information would also be too complex for beneficiaries to evaluate on their own.

APhA's concern related to medication errors is also shared by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), a group of 24 national organizations dedicated to medication error prevention and increased patient safety. The NCC MERP, which APhA is an active member of, released an official recommendation in June 2002 advising against the use of medication error rates to compare plans and other health care organizations. The Council's recommendation advises against the use of medication errors as an evaluation tool, because medication errors are not reported in the same manner and to the same degree by every organization. The definition of "medication error" adopted by each organization and the organization's reporting culture – including whether there are incentives or disincentives such as punitive action to reporting errors – can have a significant impact on the quantity of medication errors reported. The type of patient population served by the organization, as well as the type of detection and reporting systems utilized by the organization, can also have a significant impact on error rates.²² Because of these factors, it is impossible to fairly compare medication error rates between two or more plans. For example, if one plan defines medication errors broadly and actively encourages their reporting, that plan will appear to have a higher medication error rate than another plan that defines medication errors more narrowly. It would be unfair for CMS or beneficiaries to compare these two plans by comparing

²² National Coordinating Council for Medication Error Reporting and Prevention. Statement from NCC MERP: Use of Medication Error Rates to Compare Health Care Organizations is Not Recommended. Adopted June 11, 2002.

these numbers alone. The first plan would be disadvantaged simply for having a more robust medication error reporting system. For these reasons, we recommend that the Agency reconsider its proposal to evaluate plans on medication error rates.

Instead, the Agency should adopt other measures of quality assurance such as pre- and post-hospitalization medication reviews, and process and clinical outcomes related to medication therapy management services. A pre- and post-hospitalization review consists of a review of a beneficiary's medication regimen before they enter the hospital and a review of the beneficiary's medications after they are released. When a patient enters the hospital, their medication therapy is often changed. The changes may occur without regard to the patient's previous medication regimen. When the patient leaves the hospital, the patient can continue to take the new medications prescribed by the hospital (if the hospital provides an outpatient prescription for the medications), revert to the medication therapies they utilized before entering the hospital, or use some combination of the two (which can result in duplicative therapies and dangerous combinations). What medications the patient utilizes after leaving the hospital is affected by the instructions and counseling the patient receives upon discharge, as well as the formulary offered by their drug plan. A pre- and post-medication review would allow plans to identify problems with medication therapy and examine the continuity of care for their beneficiaries. Plans could enlist pharmacists to perform this review as a medication therapy management service.

The Agency should also adopt quality assurance requirements for medication therapy management programs. Quality assurance measures for MTM programs would help CMS ensure that plans are providing MTM programs as required and that those programs are generating positive health outcomes. To do that, CMS should require plans to collect and report process and outcomes measures for MTM programs. Process measures examine the plan's actions related to MTM programs and whether plans are meeting the requirements of the Act and the regulation. Suggested process measures include whether the plan established a MTM program, whether the plan identified the targeted beneficiaries that should receive MTM services, and whether those beneficiaries received those services.

Outcomes measures move beyond process measures by looking at the results of the MTM services beneficiaries receive. Requiring outcomes measures will help the plan, the Agency, pharmacists and other MTM service providers, as well as beneficiaries, determine if the MTM services are effective and at what level. Outcomes measures often include an examination of the clinical impact of the service. For example, an outcomes measure for diabetes may include regular measuring of the patient's hemoglobin A1c level. Measuring the patient's A1c level every six months will show if the MTM services are helping the patient reach and maintain their target A1c level. This type of metric can be utilized for various other chronic conditions. APhA recommends that CMS instruct plans to gather and measure the clinical outcomes of MTM services against nationally recognized treatment guidelines. To facilitate that process, a standardized minimum data set should be developed. The minimum data set would define the information or metrics a MTM provider must record and a plan must submit. For example, a minimum data set for a diabetic patient could include the patient's A1c level (the outcomes measure), the date of the MTM service, and the date of the A1c test (the process measure), as well as other additional information needed to accurately evaluate the effects of the MTM service. APhA offers its assistance to work collectively with the pharmacy profession to identify the information that should be included in a minimum data set.

Outcomes measures may also include an examination of the effects of MTM services on other areas of the health care system. For example, medication therapy management services can impact overall health care costs. Patient compliance activities may increase medication-related costs due to increased medication use, yet result in an overall reduction of health care costs due to decreased physician visits, emergency room visits, hospitalizations, and surgeries. MTM services can also impact costs outside of the health care system. For example, MTM services can help beneficiaries bring a chronic condition under control. Better management of the condition can result in fewer sick days and absences from work.

MA-PD plans are in a better position than PDPs to measure these types of outcomes, such as the effects of MTM services on overall health care costs, because MA-PD plans have access to the patient's entire medical record, not just prescription drug claims. To help PDPs evaluate the results of MTM services and to ensure that services are evaluated by the same standards, the Agency must serve as a clearinghouse for this data. APhA further recommends that CMS enlist the help of the quality improvement organizations to evaluate this data. QIOs could examine the data and help tie the effects of MTM services with other results in the health care system. We understand that QIOs do not currently fulfill this role; however, the Agency could include this requirement as part of the 8th Scope of Work for QIOs.

Medication Therapy Management Program

The Act and the proposed regulation include a requirement that plans establish a medication therapy management program (MTMP). According to the proposed regulation, the purpose of the MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. APhA strongly supports this requirement. The Association was a primary advocate for inclusion of MTM services in the Act and we appreciate both Congress' and the Agency's efforts to ensure that beneficiaries have access to valuable pharmacist-provided MTM services.

In the proposed regulation, the Agency acknowledges that it does not have extensive experience with MTM programs.²³ To better craft the MTM provision in the final regulation, the Agency has requested feedback on a number of areas, including components of MTMPs, the marketing of MTM services to beneficiaries, the identification of targeted beneficiaries, the provision of MTM services, MTM services fees, and the coordination of MTM programs with the Chronic Care Improvement Program (CCIP). APhA offers comments on each of these areas in the following section.

Scope of MTM Services

The proposed regulation includes a list of possible MTM program elements such as performing patient health status assessments, formulating prescription drug treatment plans, managing high cost "specialty" medications, evaluating and monitoring patient response to drug therapy, providing education and training, and participating in collaborative drug therapy management. APhA agrees with the MTM service examples presented in the regulation. We are pleased to see that the program elements mentioned in the proposed rule mirror many of the services included in the Medication Therapy Management Services Definition and Program Criteria developed by APhA and 10 other national pharmacy associations ([See Attachment B](#)).

²³ 69 FR at 46,668.

According to the proposed regulation, plans can customize their MTM programs – selecting the types of MTM services beneficiaries will receive and the mechanisms for their provision – within the broad framework for MTM programs that CMS provides. It appears that plans will have a great deal of flexibility in the design of their MTM programs. We are concerned that this flexibility will compromise patient care. Although plans are required to develop their MTMP in cooperation with licensed practicing pharmacists and physicians (a requirement APhA supports), there is no standard MTM benefit or minimum level of services that plans must provide or that beneficiaries can expect to receive. Without a minimum level of services plans must provide, MTM programs will vary widely from plan to plan and may compromise beneficiary's medication use. We are also concerned that plans may adopt one or two basic MTM services without regard to the specific needs of the individual beneficiaries, and technically meet CMS' requirement that plans offer a MTM program while missing the intent to connect pharmacists and patients to improve medication use and advance patient care.

Similar to the minimum requirements for formulary coverage, APhA recommends that CMS develop a minimum package of MTM services that plans must provide. The minimum package should include a broad range of professional services designed to optimize therapeutic outcomes for individual patients. A panel of experts including practicing pharmacists and physicians, representatives from health care organizations, representatives from third party payors, and beneficiaries could be convened to advise the Agency on the services a plan must, at a minimum, include in its MTMP. CMS could also enlist the help of the panel of experts when evaluating plan bids related to MTM services and measuring MTM service quality and outcomes.

Marketing of MTM Programs to Beneficiaries

In the proposed regulation, CMS requests comments on “what measures and information on effective MTMP services could be publicized and used by beneficiaries who wish to use these services?”²⁴ As discussed above under “dissemination of plan information,” APhA believes that beneficiaries should have access to information about a plan's MTM program before enrolling in the plan. Access to basic information on the plan's MTM program including information on who is eligible for MTM services, what MTM services the plan offers, and the pharmacies where beneficiaries can access these services, could help beneficiaries evaluate and select a prescription drug plan. We recommend that CMS include this information on the www.Medicare.gov website and require plans to include this information in their marketing materials and enrollment packets.

Once the MTM programs are operational, plans should be required to report information on their MTM programs, including outcomes data, to CMS through a Quality Improvement Organization. After evaluation of the information by the QIO, a summary of the plan's success at improving patient outcomes should also be made available to beneficiaries through Medicare's consumer website.

Targeted Beneficiaries

Under the proposed regulation, plans are not required to provide MTM services to every beneficiary enrolled in the plan. Instead, plans are allowed to target beneficiaries most at need for MTM services. “Targeted beneficiaries” would include beneficiaries who have multiple chronic diseases, are taking multiple covered Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines. In the preamble, the Agency questions if it should provide guidance to plans in defining “multiple chronic diseases” and “multiple covered Part D drugs,”

²⁴ 69 FR at 46,668.

or if the determination should be left to plans. If CMS leaves this determination to plans, each plan will set different minimum requirements. A beneficiary with two chronic diseases and two covered Part D drugs may qualify for MTM services under one plan, while another plan may require a beneficiary have a minimum of five chronic diseases and five covered Part D drugs in order to qualify. CMS should define multiple chronic diseases and multiple Part D drugs. We recommend that CMS set the definition for “multiple” under each requirement as “two or more”. There is precedent for the Agency to set “multiple” as two or more; a multiple source drug is defined as two or more equivalent drug products.²⁵

The remaining criterion, that beneficiaries are likely to incur annual costs for covered Part D drugs that exceed a predetermined level, is more challenging. The Act directed CMS to set the level of annual costs that a beneficiary must incur in order to qualify for MTM services; however, in the proposed regulation CMS states that it prefers to delegate the determination of high annual costs to the plans. APhA understands the Agency’s hesitancy to set a “high annual cost” amount. One national cost threshold may not be appropriate; prescription drug costs vary by region of the country. Beneficiaries who live in an area of the country where drug prices are generally lower would be penalized by having to wait longer before they meet the minimum threshold. Rather than establishing one national threshold, we suggest that CMS provide plans guidance on how to define high annual costs. For example, CMS could recommend a \$2,000 annual cost threshold but allow plans the option to offer MTM services to patients with lower projected annual costs.

Or, the Agency could consider an alternative in which plans examine the total projected costs for the beneficiaries enrolled in their plan. The plan then determines eligibility based upon where the beneficiaries fall within the plan’s overall cost range. For example, the top 30% of beneficiaries who are projected to incur the highest costs would automatically be eligible for MTM services. The next 20% of beneficiaries would also be eligible for MTM services, but the services may be less extensive, and so on. This alternative, however, is not ideal because it places too much emphasis on costs. Costs are a poor indicator for who would benefit most from MTM services. Rather, the emphasis should be placed on the beneficiary’s multiple chronic conditions and multiple medications.

Regardless of the method the Agency selects, it is important that plans keep the cost threshold low. At a minimum, beneficiaries should be targeted for MTM services before they reach the typical \$2,250 coverage limit. Properly managing a beneficiary’s treatment through MTM may keep the beneficiary out of the “doughnut hole,” or at least increase the likelihood that their medications are yielding expected results.

While the proposed regulation provides basic criteria beneficiaries must meet in order to be considered “targeted beneficiaries,” the regulation does not address how the beneficiaries will be identified. Both the plan and the beneficiary’s personal physician and pharmacist should identify beneficiaries. When plans identify targeted beneficiaries, the plan should alert pharmacists who is eligible and should be targeted for MTM services. The plan should also be required to inform the beneficiaries that they are eligible and tell them about their choices for obtaining MTM services. Once a beneficiary’s eligibility for MTM services has been determined, the beneficiary should remain eligible for MTM services for the remainder of the plan year. It is important that we avoid situations where a beneficiary qualifies for MTM, but the MTM services are so successful that the beneficiary no longer meets all of

²⁵ Section 1927 (k)(7)(A)(i) of the Social Security Act.

the eligibility criteria because of a decrease in the number of medications or annual drug spend, and is dropped from the MTM program. Without the MTM program, the beneficiary's health conditions are likely to return or worsen. Plans should be required to examine their enrollees and identify new targeted beneficiaries once a month.

A patient's personal pharmacist and physician should also be allowed to identify targeted beneficiaries. Health care professionals work closely with beneficiaries, are intimately aware of their patients' needs, and are in an ideal position to recommend that plans enroll beneficiaries in the MTM program. Identification of targeted beneficiaries by pharmacists has a history of success. For example, a two-year demonstration project in Iowa examined the impact of pharmaceutical care delivery in the community pharmacy setting. Under the demonstration project, pharmacists identified eligible patients "based on the pharmacist's knowledge of the patient's conditions," age, insurance status, and possession of at least one eligible chronic disease. At the conclusion of the demonstration project, overall health care costs for targeted beneficiaries decreased by an average \$232 per patient and health outcomes improved.²⁶

The success of the Iowa demonstration project and other MTM programs illustrates the beneficial role MTM services play in improving health outcomes. While the proposed regulation only directs plans to provide MTM services to targeted beneficiaries, it is important that other beneficiaries can access these vital services. Pharmacists must be able to offer MTM services to other non-targeted beneficiaries. Non-targeted beneficiaries would voluntarily choose to receive the services and pay the pharmacist or other provider directly. To ensure that pharmacists can continue to offer MTM services to non-targeted beneficiaries, CMS must clarify that plan contracts cannot prohibit pharmacists from providing MTM services to non-targeted beneficiaries, at the expense of the beneficiary. Pharmacists would have the authority to bill these patients directly for these services because they are not a covered benefit under the plan. Pharmacists would of course alert patients to the cost before providing the service.

Plans should also have the option to include non-targeted beneficiaries in their MTM programs. While MTM services may increase medication-related costs due to increased compliance, MTM programs have been shown to reduce overall health care costs through reduced hospitalizations and physician visits and improved management of their disease. MTM programs will lower overall costs for integrated prescription drug programs such as MA-PD plans and for the Medicare program.

Provision of MTM Services

In the proposed regulation, the Agency states its belief that pharmacists will be the primary provider of MTM services. Pharmacists are also the only provider specifically mentioned in the MTM provision of the Act. APhA greatly appreciates both Congress' and CMS' recognition that pharmacists are the most appropriate health care professionals to provide MTM services and help beneficiaries optimize their medication use. Pharmacists have a proven history of successful provision of MTM services – evidence of pharmacists' success is well documented in the literature. A few brief examples follow.

Project ImPACT: Hyperlipidemia, a three-year study conducted by the APhA Foundation, demonstrated that pharmacists, working collaboratively with patients and physicians, could help

²⁶ Impact of Pharmaceutical Care Delivered in the Community Pharmacy Setting: Results of a Two Year Demonstration Project. Pg. 3.

patients achieve their National Cholesterol Education Program (NCEP) goals. Community pharmacists in 12 states worked with 397 patients to increase patient compliance with medication therapy and work toward achievement of their target therapeutic goals. At the conclusion of the study, the rates of patient persistence (93.6%) and compliance (90.1%) were significantly higher than the national average of 40%. The number of patients who achieved and maintained their NCEP lipid goal also increased to 62.5%.²⁷

In the Asheville Project, two-employer groups contracted with pharmacists to provide asthma management and MTM services to their employees. At the end of the project, patients' clinical results had improved significantly, employer medical costs had decreased by \$1,200 per patient, and work absence rates had decreased. Both employers permanently added the benefit to their health plans.²⁸

In the Iowa Pharmaceutical Case Management Program, the state Medicaid program paid pharmacists for pharmaceutical case management of Medicaid beneficiaries with high risk of medication problems. During the program, pharmacists identified an average of 2.6 medication-related problems per patient, found drug-drug interactions in 75% of elderly patients taking antihypertensive medications, and decreased inappropriate medication use in elderly patients by 24%. At the conclusion of the program, there was no net increase in healthcare utilization or charges among patients that had received pharmacist services.²⁹

The Clinical Pharmacy Cardiac Risk Service (CPCRS), initiated in 1998 by the Kaiser Permanente Colorado Region Pharmacy Department, used pharmacists to provide a range of cardiac risk reduction services to patients with established coronary heart disease. Four years after the pilot program began, the LDL screening rate for the CPCRS was 97% and the LDL cholesterol control rate was 93%. Both numbers represented a significant improvement from the baseline and were well above national averages. It is estimated that the CPCRS outcomes will decrease the recurrence of CAD complications by 30%, saving the Colorado Region over \$9 million in hospitalizations and procedures over a six-year period.³⁰

As the examples illustrate, pharmacist-provided services have a positive impact on the health care system – improving patient outcomes while often decreasing overall medical costs. (APhA would be pleased to provide CMS with additional examples and information at the Agency's request.) Pharmacists are the ideal providers of MTM services under the Medicare prescription drug benefit. Pharmacists have the education and training to help patients manage their medication use and learn how to control their disease. Any pharmacist that is willing to provide MTM services should have the option to do so – Many MTM services can be effectively provided by any pharmacist who has a direct relationship with the patient. Of course, just as with the current medical service model, patients with more complex conditions or therapeutic regimens may benefit from services delivered by a pharmacist with documented advanced level experience, training, and skill in their area of treatment. While we recognize that other “qualified health care professionals” may also provide MTM services, MTM services must fall within the providers' scope of practice to deem them “qualified.”

²⁷ Bluml, Benjamin, et al. Pharmaceutical Care Services and Results in Project ImPACT: Hyperlipidemia. *Journal of the American Pharmaceutical Association*. Vol. 40, No. 2. Pgs 157-165.

²⁸ The Asheville Project. *Pharmacy Times*. Romaine Pierson Publishers, Inc. Westbury, NY. October 1998.

²⁹ Report of the Program Evaluation. Iowa Medicaid Pharmaceutical Case Management Program. December 2002.

³⁰ Helling, Dennis, et al. Improving Patient Outcomes by Expanding the Roles of Pharmacists. Kaiser Permanente Colorado Region Pharmacy Department. 2003.

APhA appreciates the Agency's acknowledgement that "beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the best provider for MTM service... While population based QA and cost control measures might adequately be served by impersonal telephone services, CMS believes that telephone services are only one mode of providing MTMS. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships."³¹ APhA strongly agrees with the Agency – beneficiaries should be allowed to choose how they will receive their MTM services and from whom. For many beneficiaries who have an established patient-provider relationship with their pharmacist, allowing them to continue to work with their pharmacist and receive their MTM services during a face-to-face interaction is ideal. We request that CMS clarify in the final regulation that plans cannot disrupt established patient-pharmacist relationships and require targeted beneficiaries to obtain their MTM services from a specific provider. We also request that CMS require plans to develop an eligibility verification system so pharmacists and other providers will know if a beneficiary has already been provided MTM services.

MTM Services Fees

The proposed regulation includes a discussion of "pharmacy fees" related to MTM services. According to the regulation, plans must compensate pharmacists and other qualified providers for the provision of MTM services to targeted beneficiaries. While CMS did not establish a specific fee plans must pay pharmacists for these services, the regulation directs plans to take into account the resources and time associated with implementing the MTM program. APhA recommends that the Agency expand upon this requirement and provide plans with additional guidance in determining fees for MTM services. At a minimum, plans should be directed to base fees on the time and resources required to implement and deliver the MTM services. Plans should also be required to pay providers the same fee for the same MTM service regardless of who provides the services. In other words, plans should not be allowed to pay pharmacists at a "preferred" pharmacy a higher fee for providing the same MTM service than they pay pharmacists at a "non-preferred" pharmacy. Plans should also be prohibited from paying other health care providers more than they pay pharmacists for provision of the same services.

According to the proposed regulation, plans must describe, as part of their application, their plan to consider the resources used and time required to implement the MTMP in establishing fees. However, the regulation continues to state that plans only have to disclose to CMS "upon request" the amount of the MTM fee paid to pharmacists and other providers. It is not clear why plans are only required to provide this information "upon request." Plans should be required to provide detailed information on MTM program fees as part of their original application to CMS. CMS must have detailed information on the plan's proposed MTMP fees in order to carefully evaluate each plan's bid. The Agency must evaluate whether the proposed fee is appropriate compensation for the services provided, and if the fee is sufficient to entice pharmacists to provide MTM services. APhA urges the Agency to strengthen this provision and require plans to submit detailed information on MTMP fees as part of their plan bid.

The proposed regulation also contains a provision that CMS will investigate a plan if it receives complaints that the plan is not paying pharmacists in accordance with the fees discussed in the plan's application. APhA strongly supports CMS' authority to investigate plans who fail to pay pharmacists

³¹ 69 FR at 46,669.

the MTM service fees they are due. It is not clear, however, how this provision will work. For pharmacists to file a complaint charging that they are not being paid MTM fees in accordance with the plan's application to CMS, pharmacists would have to know the amount of the fees the plan included in its application. Based on our understanding of the regulation, pharmacists would not have access to this information. For this provision to function, the Agency must create transparency in MTM program fees. Pharmacists must know the amount of the MTM fees proposed by the plan to CMS, and plans must be required to include the MTM fee rate in its contracts with pharmacies.

APhA also requests that the Agency address the billing system for MTM services in the final regulation. Currently, it appears that CMS intends to allow plans to determine how the billing system for MTM services will operate. We are concerned that allowing each plan to establish its own billing system will result in as many different systems as there are plans – a direct conflict with the administration simplification requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). CMS should adopt standards for the billing of MTM services. Billing for MTM services should be conducted electronically and follow the requirements established under HIPAA. To be HIPAA compliant, MTM services should be billed using the Accredited Standards Committee (ASC) X12N 837, the standard format for billing provider services. The X12N 837 format is essential to track provision of services and for ongoing quality assurance. The X12N 837 format should be used in conjunction with Current Procedural Terminology (CPT) codes. CPT codes are traditionally used by providers to document the provision of specific services. Because MTM is a distinct service that may occur independent of the dispensing process, and therefore should be billed separately from the dispensing process, the pharmacy community has recommended the adoption of new MTM-specific CPT codes to the American Medical Association CPT Advisory Panel.

APhA also urges the Agency to require plans to adopt the National Provider Identifier (NPI) standard for billing purposes. We anticipate that plans will require identification of the pharmacist who provided MTM services to a beneficiary as part of the billing process. Because the NPI has been adopted as the standard identifier for all transactions with federal and state programs and in claim transactions with other third party payors, the NPI should also be used by MTM providers when submitting claims for the MTM services. We encourage the Agency to follow the National Committee on Vital and Health Statistics' (NCVHS) recommendation that the NPI be used as the primary identifier for pharmacists, and that the enumeration of all pharmacists be accelerated.³² We also recommend that CMS accelerate the enumeration process for prescribers so the prescriber's NPI can be used on prescription drug claims.

Coordination with the Chronic Care Improvement Program

The Agency has requested comment on how MTM program services provided through the Chronic Care Improvement Program (CCIP) can be effectively coordinated with MTM services provided by prescription drug plans. APhA would like to offer comment on this area, however, it is difficult to provide input at this time. Insufficient information on how the new CCI program will operate is available. Without a better understanding of the CCIP, we cannot provide suggestions on how to appropriately coordinate MTM services through PDPs and the CCIP.

The Agency may obtain information from the CCIP demonstration projects that can be used to guide the coordination process between CCIPs and MTM services offered by prescription drug plans. APhA

³² NCVHS letter to Secretary Thompson. September 2, 2004.

recommends that CMS select at least one CCIP demonstration project that includes pharmacists, in pharmacies with direct patient access, as a MTM services provider. Evaluating a CCIP demonstration that involves pharmacists, who will also be the primary provider of MTM services under prescription drug plans, will provide insight to the Agency on possible coordination efforts.

Fraud, Abuse, and Waste

APhA supports the requirement that plans provide a program to control fraud, abuse, and waste. The new Medicare prescription drug benefit will involve numerous participants – CMS, plans, pharmacy benefit managers, pharmaceutical manufacturers, providers, and beneficiaries, and components – the provision and payment for prescription drugs and other health care services, and coordination activities by vendors and third party payors. Because of the size and scope of the benefit, all of these areas offer an opportunity for fraud, abuse, or waste to occur.

One of the methods the Agency can utilize to detect fraud, abuse, or waste involves the regular auditing of plans and pharmacy benefit managers (PBMs). APhA recommends that CMS conduct regular auditing of all plans and PBMs involved with the provision of the Medicare drug benefit. The Agency should examine whether they are meeting the regulation's requirements to offer a drug benefit. For example, the Agency could evaluate a plan's formulary and look for evidence of any bait-and-switch tactics in which the plan changed the formulary, or significantly increased the prices for products on the formulary, immediately after beneficiaries enrolled; or whether or not the plan has a MTM program in place that provides MTM services to all targeted beneficiaries. CMS' audit of plans and PBMs should also examine operational issues such as the turn-around time for prior authorization approvals, how quickly plans reimburse providers, compliance with state laws, and the inappropriate switching of prescription drugs.

The inappropriate switching of prescription drugs by plans is a significant concern. As the Agency acknowledges in the preamble, plans and PBMs sometimes provide a different product than the one originally prescribed for the beneficiary without first consulting the prescriber. Sometimes the "switching" is from a brand product to a generic – a practice that may decrease the costs to both the plan and the beneficiary. However, there have been reported cases where the plan switches the patient to another high-cost brand medication. According to the allegations in these cases, plans switch the patients to the second drug in order to obtain larger rebates from the product's manufacturer even though the final cost to the patient may be higher than the originally prescribed drug.³³

To supplement the regular auditing of plans and PBMs, we recommend that CMS consider adopting additional restrictions to prevent inappropriate switching. The Agency should examine the recent settlement between 20 state attorneys general and a PBM. Under the settlement agreement, the PBM is prohibited from switching patients to a more expensive competitor medication, switching patients from a medication that has a generic alternative to a more expensive brand medication that does not, switching medications to avoid competition from generic medications, and switching more than once in two years within a therapeutic class of drugs for one patient.³⁴ If CMS were to adopt similar safeguards, the potential for inappropriate switching under the Medicare drug benefit would decrease.

³³ Office of New York State Attorney General Eliot Spitzer. Press Release: Express Scripts Accused of Defrauding State and Consumers Out of Millions of Dollars. August 4, 2004.

³⁴ Department of Justice. Press Release: The United States Settles its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions. April 26, 2004.

E-Prescribing

Under the Act, plans must be prepared to support the use of electronic prescribing. Although prescribers are not required to transmit prescriptions electronically, plans must be able to support e-prescribing by prescribers who choose to use it. According to the proposed regulation, e-prescribing will not be limited to a physician sending a prescription to a pharmacy. The Agency believes that e-prescribing will allow pharmacists to access electronic information on the drugs included in a plan's formulary, any tiering of the formulary, the patient's medical history, the possibility of adverse drug interactions, and the availability of lower-priced alternative medications.

APhA appreciates CMS' intention to provide pharmacists with needed information in an electronic format. Pharmacists should have real-time access to the same information as the prescriber. By providing pharmacists with the same information that was available to the prescriber, pharmacists will have a better understanding of why the prescriber selected a medication or made a specific medication-related decision. Because the electronic prescribing standards are still in development, we do not know what information will be electronically available to pharmacists. We recommend that the electronic record include the intended use for each prescription as well as information on necessary lab test results and other relevant patient information.

To promote the use of electronic prescribing and help providers overcome implementation challenges, we suggest that CMS provide funding to pharmacies to help them implement the program. In general, pharmacies are not currently prepared to receive electronically transmitted prescriptions. To prepare for the program, pharmacies will need to obtain new computer software and hardware and train the pharmacy staff. Pharmacies may be slow to adopt e-prescribing without a source of additional funding. Providing funding to pharmacies, in addition to prescribers, will help spur program adoption.

QIO Activities

Under the Act, Quality Improvement Organizations are required to offer providers, practitioners, and plans quality improvement assistance pertaining to health care services, including prescription drug therapy. APhA appreciates the inclusion of this provision in the Act. QIOs play a vital role in improving the quality of health care received in communities across the United States by providing technical assistance and best practice information to health care providers. APhA understands that the Agency intends to issue separate guidance detailing how QIOs can provide this assistance. APhA offers the following suggestions for the Agency's consideration as it develops the guidance.

The QIOs have a role to play in assessing plans' performance at a population level. One method QIOs can use is conducting retrospective drug utilization review. Because QIOs can access claims information, they are in an ideal position to review this information on a cumulative basis and help plans and providers identify inappropriate or medically unnecessary care. QIOs can also play a role in prospective DUR. While QIOs cannot help plans and providers conduct prospective DUR because it occurs at the point-of-service, QIOs can work with plans and providers to ensure that they have a good prospective DUR program in place.

We also suggest that QIOs examine the prescription drug claims submitted to the plan, specifically looking at the number of claims that are rejected and appealed. An examination of rejected claims could provide insight into the plan's claims review process. QIOs could help the Agency determine if plans are rejecting claims for valid medical reasons or if plans are rejecting certain claims as a cost savings tactic, using rejections as a barrier to prevent access to appropriate medical care. Examining

the number of prescription drug appeals may also provide insight into the adequacy of the plan's drug formulary. If the plan receives numerous appeals for the same medications, it may indicate that the plan's formulary needs revision.

For QIOs to evaluate plans' performance on any of these levels, CMS must ensure that QIOs have access to the appropriate data. It is our understanding that QIOs generally have access to data from pharmacy and medical claims. While evaluating claims information is an important component of a QIO's work, quality improvement assistance needs to move beyond a claims-based system. As discussed in the "Quality Assurance" section of this letter, APhA recommends that QIOs play a role in the evaluation of MTM programs offered by plans. To conduct this evaluation, QIOs will need access to information beyond the claims process, including process and outcomes measures. We reiterate the Association's offer to work with others in the pharmacy profession, the Agency, and the QIOs to develop the appropriate minimum data set for MTM programs. The panel of experts we recommend CMS convene to advise the Agency on the minimum services a plan must provide, to assist in evaluating plan bids related to MTM services, and measure MTM service quality and outcomes, could also be tasked with identifying this information.

Accreditation

According to the proposed regulation, plans may be deemed to meet the requirements related to pharmacy access and cost control and quality improvement programs (quality assurance, DUR, MTMP, and fraud, abuse, and waste) if they are fully accredited by a private, national accreditation organization approved by CMS.³⁵ APhA is very concerned with this provision. The proposed regulation does not contain sufficient information on how the accreditation process would work. Based on our reading of the regulation, many questions remain unanswered. Who are the accrediting organizations? How will the accrediting organizations operate? What standards will the accrediting organizations use and how will they be applied? Before the Agency can finalize this provision of the regulation, CMS must hold a public discussion of how the accrediting program would work. A public discussion will allow stakeholders to gain a better understanding of CMS' proposal, properly vet the program, and offer substantive comments on this issue to the Agency.

SUBPART F: SUBMISSION OF BIDS & MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

Plan Design

Under the proposed regulation, entities that would like to offer a Medicare prescription drug plan must submit a bid to CMS that details the plan's design. The plan design must include information on the plan's benefits including elements such as the plan's proposed formulary. According to the proposed regulation, the Agency will not approve the bid if it finds that "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan."³⁶ We question how the Agency intends to define "substantially discourage." APhA is concerned that CMS would allow plans to design a benefit that would discourage, at any level, groups of beneficiaries (such as those in rural areas or with a certain health condition) from enrolling. The Agency should not approve plan bids that are even minimally designed to discourage enrollment.

³⁵ 69 FR at 46,821. Section 423.165 (a)(1).

³⁶ 69 FR at 46,825. Section 423.272 (b)(2).

SUBPART J: COORDINATION UNDER PART D WITH OTHER PRESCRIPTION DRUG COVERAGE

Billing Coordination

APhA supports the requirement that plans permit State Pharmaceutical Assistance Programs (SPAPs) and other drug plans offered through Medicaid, group health plans, the Federal Employee Health Benefits Plan (FEHBP), and military coverage, to coordinate coverage with the Medicare prescription drug benefit. Allowing providers of other prescription drug coverage to voluntarily coordinate their benefits with Medicare will result in a higher level of drug coverage for beneficiaries enrolled in both the Medicare program and another plan. This coordination will be extremely valuable for low-income beneficiaries. SPAPs and other drug programs may elect to pay beneficiaries premiums and/or co-insurance, or provide coverage on a claim-specific basis.

We are concerned, however, that the coordination of prescription drug coverage provided by Medicare, SPAPs, and other drug plans will fall onto the pharmacist. When some level of prescription drug coverage is provided through Medicare and another drug plan, the pharmacist will have to determine which plan is the primary versus secondary payor, how much to bill each plan, and how much to charge the beneficiary. It will be extremely difficult for pharmacists to coordinate these billing arrangements for a program as large as Medicare, especially because pharmacists will likely be working with many different Medicare prescription drug plans within their region. Pharmacists are not prepared to take on this additional administrative burden without increased reimbursement and program parameters to decrease administrative burden. Coordination of benefits by pharmacists may be cost-prohibitive if plans implement the current claims process in which pharmacies are charged each time they file a claim. Because pharmacists would have to file multiple claims to bill both the primary and secondary payors, pharmacies would face multiple charges for each prescription they dispense. We urge the Agency to address these concerns when developing the coordination of benefits system.

The system must provide necessary information – information on secondary payors, the correct billing order, the amount to bill each payor, and the correct beneficiary co-payment – to pharmacists in a real-time format. The coordination of benefits system must also be standardized so that it operates in the same manner for all drug benefit plans, and it must accurately track costs that should be attributed to a beneficiary's true out-of-pocket expenditures. APhA encourages CMS to work with the State Pharmaceutical Assistance Transition Commission (SPATC) to explore possible coordination issues with Medicaid and state pharmaceutical assistance programs.

SUBPART M: GRIEVANCES, COVERAGE DETERMINATIONS, & APPEALS

Formulary Appeals

As previously discussed, the proposed regulation includes a requirement that plans establish an exceptions process for non-formulary medications. APhA reiterates its request that the Agency establish a standardized exceptions process for use across all Medicare prescription drug benefit plans. Requiring one standardized appeals process will help prescribers, pharmacists, and beneficiaries better navigate the exceptions process. The Agency should also clarify that the beneficiary's costs apply towards the total true out-of-pocket (TrOOP) expenditures if the formulary appeal is approved.

SUBPART P: PREMIUM & COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Transition from Medicare to Medicaid

When the new Medicare prescription drug benefit takes effect in January 2006, millions of dual eligible beneficiaries will begin receiving their prescription drug benefits from the Medicare program instead of Medicaid. The transition from the Medicaid program to Medicare will be a tremendous undertaking. It will require substantial effort to identify these beneficiaries, enroll them, and remove them from the Medicaid roles. Dual eligibles may also find it difficult to adjust to the switch from the Medicaid program and may need additional assistance understanding the new administration of the new benefit and the new services, such as MTM, that are available to them. To prepare for the transition, APhA recommends that the Agency begin working with State Medicaid agencies, SPAPs, and state pharmacy associations to begin the identification of dual eligibles. We also recommend that the Agency create and launch a new educational campaign targeted at this group of beneficiaries to explain the transition process. In recognition of the role pharmacists and other providers will play in benefits consultation for this population, we also request that CMS compensate providers for these services.

Administration of Subsidy Program

The new Medicare drug benefit will provide significant assistance for low-income beneficiaries. Depending upon income level and assets, beneficiaries with incomes below 150% of the federal poverty level are eligible for premium and cost-sharing subsidies designed to reduce their out-of-pocket costs. Under the proposed regulation, states are responsible for determining what individuals are eligible for a full or partial low-income subsidy. Plans must then reduce eligible beneficiaries' premiums and cost-sharing as applicable. It is our understanding that the Agency will reimburse plans for the amount of the reduction in premium or co-payment. APhA is concerned because the regulation neglects to explain how the reimbursement for reduced co-payments will be passed through to the pharmacy. Subsidy eligible beneficiaries will receive a reduction in co-insurance at the point-of-sale.

The pharmacy will reduce the co-payment as instructed by the plan and the plan will receive reimbursement from CMS for the reduction. However, there does not appear to be a requirement that the plan pass through the reimbursement to the pharmacy. For example, a partial subsidy beneficiary must only pay a reduced co-insurance amount of 15% instead of the normal 25%; therefore, the pharmacy receives a smaller payment from the beneficiary. CMS will then reimburse the plan for that 10% difference. The Agency appears to assume that the plan will pass this payment through to the pharmacy. Without an explicit requirement that plans pass through the money received for reduced co-insurance, plans are under no obligation to reimburse the pharmacy. APhA requests that CMS add a pass through requirement to the final regulation.

In conclusion, APhA is generally supportive of the proposed regulation. The Agency has done a commendable job in crafting regulations to implement this historic prescription drug benefit. The Act and the implementing regulations will increase Medicare beneficiaries' access to necessary medication therapies and to valuable pharmacist-provided medication therapy management services. Increasing access to prescription drugs and the services that help beneficiaries make the best use of these medications will have a tremendous impact on health outcomes and the overall health care system. To implement the most effective benefit, however, the Agency must revise the regulation in several key

areas. APhA has offered recommendations for these revisions throughout this comment letter. Rather than reiterate all of our suggestions, we will highlight some of the most significant here.

As the health care professional most closely connected with the provision of prescription drugs, pharmacists will play a large role in the Medicare prescription drug benefit. Pharmacists will educate beneficiaries about the new benefit, help them evaluate prescription drug plans, explain the transition from Medicaid to Medicare for low-income beneficiaries, help coordinate the benefit among multiple payors, and perform other new benefits consultation duties. APhA requests that CMS revise the final regulation to recognize these services – and the time and effort – pharmacists will spend providing them, and compensate pharmacists appropriately.

We insist that the Agency strengthen the provisions intended to preserve beneficiaries' access to the pharmacist and pharmacy of their choice. CMS must strengthen the pharmacy access standard requirement and require plans to measure compliance with the standards on a local level to ensure convenient access to community pharmacies for all beneficiaries. If plans are allowed to designate "preferred" and "non-preferred" pharmacies, the Agency must clarify that non-preferred pharmacies do not count when assessing a plan's compliance with the access standards. And the Agency must instruct plans that the cost differential for extended supplies obtained through community versus mail service pharmacies must be limited to the difference in providing the service, not the cost of the drug product.

APhA also requests that the Agency put requirements in place to ensure that beneficiaries receive the majority of savings plans negotiate with pharmaceutical manufacturers. As the regulation is currently drafted, plans must offer beneficiaries access to negotiated prices, but plans are not required to share a specific portion of the negotiated price concessions with beneficiaries. CMS should require plans to pass through at least 75% to 80% of savings to beneficiaries. The regulation must also address the reimbursement process for pharmacies. Plans should be required to reimburse pharmacies at a fair and adequate rate, and share a portion of the negotiated price concessions with pharmacies to compensate them for offering drugs at a lower price. Reimbursement to pharmacies must also be made on a timely basis – within 30 days from the date of claim submission.

APhA strongly supports the requirement that plans establish a medication therapy management program and compensate pharmacists for providing these services to targeted beneficiaries. We are concerned, however, that the proposed regulation appears to provide plans with too much flexibility in the design of their MTM programs. APhA requests that CMS develop a minimum package of services plans must provide, set the definition of "multiple chronic diseases" and "multiple chronic drugs" as two or more, and provide plans with guidance on determining "annual high costs." The Agency should also clarify that both the plan and the beneficiary's pharmacist and physician can identify targeted beneficiaries, that the plan must identify new beneficiaries every month, and that once identified, beneficiaries should remain eligible for the entire year. Beneficiaries must be allowed to receive MTM services from the pharmacist of their choice, and plans must be required to pay providers the same fee for the same service regardless of who provides the services.

Finally, we request that the Agency include standardized processes where possible in the final regulation. The new drug benefit will be offered by a number of different plans and providers will likely work with several of them. It will be extremely difficult for pharmacists and other health care professionals to learn to navigate the various requirements for each program. Providers should not be

required to learn different requirements for each plan. APhA recommends that CMS establish standard processes for formulary exceptions, claims submission, the coordination of benefits, the reporting of quality assurance measures, and other provisions of the regulation that apply to all PDP and MA-PD plans.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or <mailto:SWinckler@APhAnet.org>, or Susan K. Bishop, Senior Manager, Regulatory Affairs & Political Action, at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,

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