CMS Responses to Recommendations made by the State Pharmaceutical Assistance Transition Commission

1. State Pharmaceutical Assistance Programs (SPAPs) should be allowed to endorse one or more preferred Part D plans for their enrollees. Section 1860D-23(b)(2) of the Social Security Act (the Act) defines an SPAP, in part, as a program that "in determining eligibility and the amount of assistance to Part D enrollees, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled." We are interpreting the non-discrimination language at 42 CFR 423.464(e)(1)(ii) of our final rule to mean that in order for an entity to meet the definition of an SPAP, and have its payments for supplemental assistance for Part D cost sharing count as true out-of-pocket costs, it must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the state but also may not steer beneficiaries to one plan or another through benefit design or otherwise. We believe the law intends that all Part D plans have an equal chance to enroll beneficiaries throughout a region, including in states with SPAPs.

We will be issuing further guidance to help SPAPs understand how they can ensure that their outreach, education, and benefits are non-discriminatory. As part of the SPAPs' education and outreach process we encourage SPAPs to assist beneficiaries in determining which plan formularies include drugs that the SPAP beneficiary is currently using and to provide the beneficiary with the information necessary to allow the beneficiary to choose the most favorable plan. In addition to the formulary, the SPAP should also help beneficiaries with understanding a plan's drug tiers, premiums and network pharmacies in each Part D plan.

2. SPAPs, at their own option, should be allowed to determine eligibility for low-income subsidies. Section 1860D-14(a)(3) of the Act requires that determination of eligibility for the low-income subsidy program be determined under the state plan under title XIX (Medicaid) or by the Commissioner of the Social Security Administration (SSA). While the law is clear that either the Medicaid agency or SSA is responsible for determining low-income subsidy eligibility, SPAPs are encouraged to play a vital role in assisting low-income beneficiaries when applying for the low-income subsidy program. CMS encourages SPAPs to assist their beneficiaries with the SSA or state application process for the low-income subsidy. SPAPs can also use the low-income subsidy application to determine SPAP eligibility so beneficiaries will not have to submit two separate applications; one for the low-income subsidy and then one for the SPAP.

3. The final Part D regulation should eliminate or allow exclusions to the asset test. Section 1860D-14(a)(3) provides specific resource requirements in order for an individual to qualify for the low-income subsidy. Therefore, the regulations cannot eliminate this legislative mandate. However, in regard to the asset test for the low-income subsidy program, we believe Congress envisioned a simplified application process. Therefore, in order to keep the process simple and minimize administrative cost we will only consider liquid resources (that is, those that could be converted to cash

within 20 days) and real estate that is not an individual's primary residence, as resources available to the applicant.

4. Marketing, enrollment, and educational materials should include clear and concise explanations of how the SPAP and the prescription drug plan (PDP) sponsor will coordinate prescription benefits. We agree that informational materials explaining how the drug benefit will work with the SPAP benefit should be clear and understandable. Because each SPAP may choose to coordinate with Part D plans in different ways, SPAPs will be responsible for customizing materials for their enrollees. To assist SPAPs, CMS will provide guidance by July 1, 2005, on the requirements for benefit coordination that Part D plans must meet. Additionally, we have established an SPAP Work Group with state representatives of these programs in order to help us understand the needs of SPAPs and to develop guidance for states on educating beneficiaries and providing wrap-around coverage for their SPAP members. Plans will also have the ability to co-brand materials (place the SPAP logo on the plan's i.d. cards and marketing materials) where the plans deem appropriate, and to equip beneficiaries with appropriate, understandable information about both their Part D and SPAP benefits.

5. The final Part D regulation should allow an SPAP to automatically enroll its beneficiaries into one or more preferred PDP sponsors. As noted above, the statute at section 1860D-23(b)(2) of the Act and the final regulation at 42 CFR 423.464(e)(1) provide that if an SPAP enrolls its members in a preferred plan in a manner that discriminates among available Part D plans, its financial contributions will not count as true out-of-pocket costs for its members. We believe the law intends that all prescription drug plans be given comparable opportunities to participate in the program, thereby promoting competition among plans that want to provide benefits in a region. This will provide a variety of good choices for all people who are eligible for the program, including those enrolled in SPAPs. We are committed to working with SPAPs to help their members understand their options for accessing affordable prescription drug coverage under the Medicare program.

6. CMS should include safeguards for all vulnerable populations against ill-advised disenrollments and should notify each coordinating SPAP of all disenrollments of that SPAP's beneficiaries. While we understand the concern about providing safeguards for vulnerable populations, it is important to note that enrollment in Medicare Part D is voluntary. In our final regulation at 42 CFR 423.36(b), we describe our requirements for voluntary disenrollment. Plans must submit a disenrollment notice to CMS, provide the enrollee with appropriate notice, and file and retain disenrollment requests. We are developing model language for this disenrollment notice, which will help beneficiaries understand that they are no longer enrolled and may no longer access benefits from the plan as of the disenrollment effective date. Since Part D plans are required to coordinate with SPAPs, we will consider the need for additional enrollment and disenrollment information as we develop operational guidance in this area.

7. Final Part D regulations should provide for a process similar to the Medicare Part B buy-in to allow states, at their option, to pay Medicare Part D premiums on behalf of SPAP beneficiaries. SPAPs will be permitted to pay premiums and cost sharing on behalf of Medicare beneficiaries. Because Part D premiums are collected by Part D plans, SPAPs will need to pay premiums directly to the prescription drug plans. It

should also be noted that premiums must also be paid in a non-discriminatory basis. That is, SPAPs must offer premium assistance to all beneficiaries, regardless of the plan they are enrolled in.

8. SPAPs that pay premium costs, including late fee penalties, on behalf of their beneficiaries should pay minimal late enrollment penalties. As a consequence of late enrollment in a prescription drug plan, an individual may be responsible for paying a higher premium. Since the higher premium is based on a calculation that is uniform for all beneficiaries (except full-subsidy individuals), we do not have the authority to reduce the amount an individual is required to pay. If the beneficiary qualifies as a full subsidy eligible individual, the individual receives an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of the late enrollment penalty thereafter. Therefore, if an SPAP chooses to pay the premium on behalf of such beneficiaries, it will be responsible only for 20 percent of the late enrollment penalty for the first 60 months. For all other Part D beneficiaries, the SPAP, if it chooses, will be responsible for paying the entire amount of the late enrollment penalty.

9. PDP sponsors should be required to submit network plans that offer the same cost-sharing requirements for all in-network pharmacies. The MMA and our regulations afford Part D sponsors the flexibility to vary cost-sharing for certain pharmacies within their networks, provided they meet the relevant actuarial equivalence tests and such designs do not increase CMS payments to plans. Therefore, we cannot require that Part D sponsors apply the same cost-sharing in all pharmacies in their network.

10. CMS should clarify that the geographic standards for access apply in each zip code, not just on average across all urban, suburban, rural areas in the defined region. As discussed in our final rule for Part D, we have determined that the best way to effectively balance convenient beneficiary access to network pharmacies with Part D sponsors' ability to meet our pharmacy access standards is to apply our retail pharmacy access standards across all urban, suburban, and rural areas in each State in which a prescription drug plan or regional MA-PD plan operates, or, in the case of a MA-PD local plan, in its service area.

11. PDPs should be required to approach any willing (long-term care) LTC pharmacies in the service area for participation in a plan's network. Any LTC pharmacy that meets certain performance and service criteria, which we will define in separate guidance, must be allowed to participate in the Part D sponsor's LTC pharmacy network.

12. The definition of LTC facility should be broadened to include intermediate care facilities for the mentally retarded (ICFs/MR), intermediate care facilities for the developmentally disabled (ICFs/DD), assisted living, and other supportive housing facilities, including group homes under 1915(c) home and community based waivers. We have expanded the definition of an LTC facility in our final regulations to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Social Security Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section

1902(q)(1)(B) of the Act. Such expansion would encompass all ICFs/MR and inpatient psychiatric hospitals along with skilled nursing and nursing facilities, provided those facilities meet the requirements of a medical institution that receives Medicaid payments for institutionalized individuals under section 1902(q)(1)(B) of the Act. We do not believe that the definition of long term care facility should be expanded to include other facility types recognized by state law (like group homes) but not by Medicare or Medicaid, even though some of these facilities contract on an exclusive basis with long-term care pharmacies.

13. CMS should establish a standard policy and set of procedures for all prescription drug plan (PDP) sponsors addressing the acceptable grounds for using an out-of-network pharmacy, and how the claims will work. Our out-of-network policy requires a Part D plan to ensure that a beneficiary can access a covered Part D drug at an out-of-network pharmacy when that beneficiary cannot reasonably be expected to obtain that drug at a network pharmacy. Plans will establish their own out-of-network access policies consistent with this requirement. Given that claims processes for out-of-network pharmacies will not be electronic, beneficiaries will have to pay out-of-pocket for the usual and customary price of the drug purchased out-of-network and submit a paper claim to their Part D plan. Plans will reimburse the plan-allowable amount for the drug plus any low-income subsidy cost-sharing assistance.

14. The final regulation should make it clear that any price differential, paid for retail versus mail order, would count as an incurred cost toward the out-of-pocket threshold (TrOOP) for the enrollee, whether paid by the enrollee or the SPAP. Our regulation clarifies that any amount spent by the enrollee, another person on the beneficiary's behalf (including a qualified SPAP) other than a group health plan, insurer, government-funded health program, or similar third party arrangement, will count as an incurred cost toward TrOOP as long as the expenditure is made for a covered Part D drug.

15. SPAPs will need to consider how they will handle snowbirds and establish appropriate policy on a state by state basis. We agree that SPAPs should establish a policy on how to handle beneficiaries who spend an extended time away from the plan's service area.

16. The regulations should also require the PDP sponsors to detail their visitor/traveler benefits to members and SPAPs. Visitor/traveler benefits will be detailed by Part D plans in both the Summary of Benefits and Evidence of Coverage documents.

17. SPAPs should carefully evaluate the adequacy of formularies of the PDP sponsors available to their enrollees. CMS will be performing the formulary review function to ensure that plans offer adequate benefits to serve the needs of beneficiaries. CMS has posted detailed formulary guidance on our Web site that outlines our principles and processes for reviewing formulary submissions.

18. Special transition rules should be established for the early months of 2006 to ensure continuity of care for persons newly enrolling with PDP sponsors. To address the needs of new plan enrollees who are transitioning to the Medicare benefit from other prescription drug coverage, and whose current drug therapies may not be included in their

plan's formulary, we are requiring that plans establish an appropriate transition process for new enrollees.

19. PDP sponsors should share data and enter into agreements regarding continuity of care and coordination of such things as prior authorization, generic substitution and formulary changes. In accordance with section 1860D-23(a)(1) of the Act, CMS will be issuing guidelines by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage for payment of premiums and coverage and payment for supplemental prescription drug benefits. These requirements will specify the specific coordination elements that Part D plans must share with SPAPs and other prescription drug coverage, and the means for doing so. PDPs will not be required to enter into contracts with other plans.

20. Mid-year formulary changes should be discouraged. Part D plans can only change categories and classes at the beginning of the plan year unless newly approved Food and Drug Administration (FDA) drugs require the addition of a new category or class. With respect to removing a specific drug from the plan formulary or making any change in a drug's preferred or tier status, plans will need to provide CMS and affected enrollees with 60 days notice of the forthcoming formulary changes (with the exception of drugs deemed unsafe by the FDA or removed from the market by the manufacturer, which immediately may be removed from the formulary). This will allow enrollees sufficient time to pursue exceptions if necessary or transition to alternative drugs. Experience under commercial prescription drug benefits suggests that there is no reason to anticipate much mid-year change in formularies except to accommodate new drugs that come on the market or drugs that are withdrawn for reasons of safety.

21. If mid-year formulary deletions are allowed, a 90-day notice provision should be adopted (rather than the proposed 30-day notice) to ensure continuity of care for beneficiaries and to aid SPAPs in any programmatic changes they need to engage in when a formulary changes in a Part D plan. The final regulation requires a 60-day notice prior to any removal of a drug from a plan's formulary (other than drugs deemed unsafe by the FDA or removed from the market by the manufacturer).

22. If mid-year formulary deletions are allowed, CMS should require that PDP sponsors certify that their proposed changes in formulary do not change the actuarial value of the benefit or the compliance of the formulary with U.S. Pharmacopoeia and CMS standards, including two drugs per class and non-discrimination. CMS will evaluate all mid-year formulary changes to ensure that the plan's formulary continues to comply with all applicable requirements.

23. The Commission agrees with CMS that certain populations' needs for continuity of care trumps formulary design. Part D enrollees will have access to all medically necessary drugs. Numerous safeguards, including our formulary requirements, formulary review, transition requirements, and exceptions and appeals requirements, will ensure that this is the case. Please refer to our detailed formulary guidance posted on the CMS Web site (www.cms.hhs.gov/pdps/) for our approach to ensuring that all beneficiaries, and especially vulnerable populations, have access to their medically necessary drug therapies.

24. CMS should explore setting up a retrospective medical necessity review framework in lieu of formulary denials, to protect the health of the patient and ensure minimal disruption and continuity of care. Part D plans will have the discretion to set formularies and design their own quality assurance reviews as long as they meet the requirements set forth in the Part D statute and implementing regulations. Since the MMA gives Part D plans the option to set formularies, CMS does not have the ability to require that Part D plans have a retroactive medical necessity review in lieu of formulary denials, as suggested.

25. SPAPs should be specifically identified in the regulations or statute as authorized representatives to file exception requests and appeals to the PDP sponsor. There is no statutory authority to specify in the regulation that SPAPs may be considered authorized representatives of enrollees. However, 42 CFR 423.560 provides that an enrollee may appoint any person or entity to act on his or her behalf in filing a coverage determination or any appeal. Thus, nothing in the regulation would prohibit an enrollee from appointing an SPAP as his or her representative. Alternatively, if under state law an SPAP has the authority to act on behalf of its enrollees with respect to their Part D coverage, including the filing of exceptions and appeals, the SPAP may be considered an authorized representative of its enrollees and may file an exception or appeal on their behalf.

26. Dispensing pharmacists should also be allowed to act as authorized representatives to request exceptions on behalf of enrollees. See response to 25.

27. Section 42 CFR 423.562 of the proposed regulation should be revised to clarify that if an SPAP has paid for a drug, this in no way eliminates the beneficiary's or SPAP's right to pursue an appeal for coverage of the drug by the PDP sponsor. We agree with this recommendation and have revised the language at 42 CFR 423.562 to provide appeal rights to an enrollee when he or she has no further liability to pay for prescription drugs furnished through a Part D plan. This will permit SPAPs, as well as other secondary payers, authorized to act as the enrollee's authorized representative, to appeal coverage decisions made by the Part D plan.

28. Give SPAPs the authority to challenge a PDP sponsor's pattern of decisions on a class of drugs, first by formally contacting the PDP sponsor and asking for a re-consideration of its policies and criteria, and secondly, if the first effort as resolution fails, by appealing to the independent review entity. We are required by the MMA to model the Part D grievance and appeals procedures after the Part C grievance and appeals procedures. Part C does not provide the suggested type of appeals process. In addition, neither the MMA nor the applicable provisions of the Act provides for the type of appeals process suggested. As a result, we do not have the statutory authority to create a formal appeals process that would allow SPAPs or other entities to challenge a plan sponsor's pattern of decisions. However, as noted in our response above, we have revised language at 42 CFR 423.562 to permit SPAPs, as well as other secondary payers authorized to act as the enrollee's authorized representative, to appeal coverage decisions made by the Part D plan.

29. Require PDP sponsors, at least for dual eligibles, low-income subsidy beneficiaries and SPAP enrollees, to pay for a 3-day emergency supply of denied

medications to enable the patient to have time to contact their physician for a prescription for an alternative formulary medication or to appeal, and to pay for a continued supply of any medication that is under appeal, in order to prevent a break in therapy. In addition to requiring that Part D plans have safe and reasonable transition plans (on which more guidance is imminent), we have significantly shortened the timeframes for making coverage determinations and appeals. We require plans to make determinations as expeditiously as an enrollee's health condition requires, and, in cases where the enrollee's health could be seriously jeopardized, the plan must make a coverage determination within 24 hours. This should ensure that enrollees do not experience delays in receiving necessary medications. Also, because we require plans to either provide affected enrollees with advance notice of a formulary change or a 60-day supply of a medication affected by a formulary change, enrollees will not be faced with any lapses in coverage of a medication that they are already taking. This requirement enables enrollees to obtain determinations on formulary exceptions and appeals before their 60-day supply ends.

30. Require PDP sponsors to respond to requests for exception & prior authorization over the phone or within 24 hours (as in Medicaid*)* to avoid delays and breaks in care, and to avoid putting SPAPs on the spot to pay the full cost. The final rule requires plans to respond to expedited requests for exceptions within 24 hours, and standard requests within 72 hours. Plans may choose to notify enrollees (and prescribing physician involved, as appropriate) in writing or orally. If the plan first notifies the enrollee orally, it must send a written confirmation within 3 calendar days.

31. Provide SPAPs with information about why a PDP sponsor claim is denied, so that the SPAP can decide whether to appeal. Consistent with the Part C notification procedures, notification of a determination is sent to an enrollee, the prescribing physician involved (as appropriate), or an appointed representative. The notification includes, among other types of information, the reason(s) for the denial. If an SPAP is an enrollee's appointed representative, it will receive notice of a determination.

32. Cases reviewed by the independent review entity (IRE) should be reviewed de novo, and not limited to ruling only on whether the PDP sponsor applied its own criteria appropriately, as suggested in the proposed regulations. As stated in the preamble, we agree that the IRE's review must not be limited to whether a plan applied its exceptions criteria correctly. Plans' exceptions procedures must include measures to grant an exception when the plan determines that an exception would be medically appropriate. Because these determinations will be subject to review by the IRE, the IRE will necessarily also review whether a drug is medically necessary. Therefore, the IRE's medical staff also must review the plan's medical necessity determination in addition to whether the plan properly applied its exceptions criteria for the individual in question. Examining the record de novo using the plan's exceptions criteria, as approved by us, and making an independent medical necessity determination will form the basis for the IRE's decision. However, the IRE is prohibited from ruling on the validity of a plan's exceptions criteria or formulary. Only CMS can evaluate and decide whether to approve a plan's exceptions criteria and formulary as part of the annual plan approval process.

33. PDP sponsors should share clinical criteria with SPAPs for approval of PA requests, exceptions, and tiered co-pay exceptions, so that the SPAPs will not waste

time pursuing appeals that will be justly denied on clinical grounds. While we cannot require PDP sponsors to share with SPAPs the clinical criteria used by the Part D plans in approving PA requests, formulary exceptions, and tiered copay exceptions, there is nothing in the law or final regulation that precludes an SPAP from requesting these criteria from the PDP sponsors. However, PDP sponsors and their plans must keep in mind that release of any patient clinical data must meet HIPAA privacy standards if this information is shared with the SPAP.

34. PDP sponsors should be required to issue written notices of denial and appeal rights upon initial denial of a pharmacy benefit. As stated in the preamble, the transactions that occur at the pharmacy counter are not coverage determinations because the pharmacists are merely relaying information regarding a plan's benefit design, and pharmacists do not exercise any discretion on behalf of plans. However, plans are required to arrange with network pharmacies to post or distribute standardized notices (created by CMS) explaining enrollees' rights to receive, upon request, detailed written notices from plans explaining their right to request an exception if they disagree with the information relayed by pharmacists. When a plan makes an unfavorable determination, the regulations require plans to issue written notices of the determination, which includes an explanation of an enrollee's appeal rights.

35. Beneficiaries should be grandfathered or get a grace period of at least 90 days of coverage when they first trip a formulary, step therapy, dose limit, or PA denial for a drug they've been on previously. The final rule requires Part D plans to provide an appropriate transition process for new enrollees currently prescribed part D drugs not included on a plan's formulary. CMS will be issuing additional guidance on formulary transition requirements and all Part D plan applicants must have their transition policies reviewed and approved in the application process. In addition, we have provided a streamlined adjudication process which will ensure that enrollees quickly receive determinations regarding medically necessary drugs.

36. Notices of formulary deletions should be considered notices of coverage determinations, and beneficiaries should be instructed how to submit medical information in order to seek a re-determination for their case. The statute gives plans the ability to make changes to their formularies during the plan year. It also requires plans to notify affected enrollees of any such changes. In the regulation, we require plans to notify affected enrollees of any changes to their formularies or cost-sharing structures by sending a written notification to any enrollee who is using a drug affected by a change at least 60 days in advance of the effective date of the change. If the plan does not send such notice, it must provide affected enrollees with a 60-day supply of the affected medication and provide notice of the change when the enrollee requests a refill. The notice must contain, among other things, an explanation of how the enrollee may obtain a coverage determination or exception. The enrollee will have 60 days to request an exception, that is, to obtain a determination, and appeal, if necessary, or switch to an appropriate alternative medication.

37. The exception process should have a two day turn-around time to reflect current practice, as well as to serve patient needs. As mentioned previously, plans must make a decision on an exception as expeditiously as an enrollee's health condition

requires, but no later than 24 hours for expedited requests, or 72 hours for standard requests.

38. Denials of re-determinations should be sent by the PDP sponsor automatically to the IRE, as are all other benefit denials. When a plan on redetermination upholds its original denial, the redetermination is not automatically forwarded to the IRE for review. Instead, the enrollee must request a reconsideration. However, consistent with Part C, we require plans to automatically forward coverage determinations or redeterminations to the IRE for review if the plan fails to issue its determination within the applicable adjudication timeframe.

39. There should be no bifurcation in the timelines for appeals whether the recipient (or SPAP) paid for the drug or went without the medication. We revised the adjudication timeframes so that determinations that involve payment and benefit issues must be made in the same timeframe. However, only claims that involve a drug that has not yet been received and/or paid for may be expedited.

40. An expedited exceptions process should be available even when a patient has paid for the medication out-of-pocket subsequent to the denial, if further refills will be needed. Consistent with Part C, the Part D expedited process is only available to enrollees when the plan determines, or the enrollee's prescribing physician indicates, that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee, or the enrollee's ability to regain maximum function. However, as mentioned previously, we streamlined the appeals process by shortening the adjudication timeframes for coverage determinations, redeterminations, and IRE reconsiderations. As a result, enrollees who pay for medications will be able to obtain determinations sooner than originally proposed.

41. The initial claim denial should be considered a coverage determination, and a denial notice with appeal rights should be sent as a result of this coverage determination. The initial claim denial made by the plan sponsor is a coverage determination, which results in a plan issuing a denial notice that includes information regarding an enrollee's right to appeal.

42. The exception process should be considered the re-determination or at least explicitly treated as a <u>brief</u> step between the coverage determination and the re-determination. The MMA requires that the denial of a tiering exception must be treated as a coverage denial. In addition, we are required by the MMA to model the Part D coverage determination and appeals procedures after Part C. Under Part C, an appeal cannot occur until an unfavorable coverage determination has been made. Therefore, under Part D, an enrollee may not request a redetermination until an unfavorable coverage determination has been made. Therefore, an exception requesting the plan to cover a non-formulary Part D drug cannot be considered a redetermination.

43. Formulary deletions should be considered coverage determinations, as noted above. See the response to 38.

44. The projected value of a medication, for purposes of meeting the threshold to go to the ALJ, should be clarified to be projected over the full likely duration of the drug's use for that patient. In the final rule, we clarified that the projected value of a

Part D drug, for purposes of calculating the amount remaining in controversy, shall include any costs the enrollee could incur based on the number of refills prescribed for the drug in dispute during the plan year. Limiting the calculation to the costs incurred in a plan year is consistent with the statutory provision that allows enrollees to switch plans at the beginning of a new plan year.

45. The criteria for considering copay exceptions should consider the medical effectiveness and safety of the drugs and the specific clinical profiles of the appellants, as in formulary exceptions. Beneficiaries should have access to the non-preferred drug at the preferred copay rate if the preferred drug is likely to cause an adverse effect or is likely to fail to control their symptoms or disease. The regulations require plans to base their decisions regarding either type of exception on the medical necessity of the requested Part D drug when compared with the preferred or formulary drug. Consistent with the statute, except for a few narrow exceptions, the regulations require plans to provide coverage at the cost-sharing level that applies for preferred drugs when a tiering exception is approved.

46. Drugs covered through exception or appeal should have the copay of the preferred formulary drug that the PDP sponsor felt was an appropriate alternative when establishing the formulary. Consistent with the statute, the regulations require plans to provide coverage at the cost-sharing level that applies at a lower tier when a tiering exception is approved. For formulary exceptions, plans must choose (subject to review by CMS) which level of cost-sharing will apply to Part D drugs approved under the formulary exceptions process. The plan must uniformly apply that level of cost-sharing to all Part D drugs approved under the formulary exceptions process, and may not establish a special tier or other cost-sharing arrangement that applies only to drugs approved under either exceptions process. For example, if a plan chooses to apply the level of cost-sharing that applies to preferred drugs, every formulary exception that is approved must be covered at the preferred cost-sharing level.

47. Maintain a high degree of flexibility to allow SPAPs to determine the level and extent of the information they will provide to beneficiaries enrolled in these programs. In general, we do not have the authority to mandate the type of information SPAPs provide to their enrollees about the Part D program. Section 1860D-23(d) of the Act provides for grants to SPAPs in existence as of October 1, 2003, which were awarded in September of 2004 for fiscal year 2005, for the purpose of educating their members about options to access Medicare drug benefit coverage and about comparing options so they can choose the best value for them. We will reach out to SPAPs with information to help people with Medicare understand their drug plan options. We will also assist SPAPs in adapting this information to ensure that their members understand the way that the new Part D plans coordinate with their SPAP benefit and supporting their members in making informed decisions about drug benefit plan options.

48. We must take a lesson from the Medicare Drug Discount Cards and make certain there is regulation of product quality and clear, concise, appropriate and timely information available to consumers. CMS agrees and is conducting transition workgroups between the Discount Drug Card staff and the Drug Benefit staff to apply what was learned to the Medicare Drug Benefit.

49. Educational materials and campaigns must be developed with the recognition that not only are SPAPs diverse in their methods of operation, but that the consumers represent age and ethnic diversities which must be considered in developing education campaigns and materials. CMS agrees. The regulation of Part D marketing will be very similar to the Medicare Advantage (MA) marketing regulatory program. The demographics of the MA marketing audience are very similar to those of the SPAPs and CMS will take this into consideration throughout the development of educational materials and campaigns.

50. Develop a specific strategy to target dual eligibles. CMS is developing a specific strategy to get information to those who are dual eligibles. Currently, CMS is working with other Federal agencies and with partners to build awareness. The following is a schedule of outreach activities targeted to the low-income subsidy population including dual eligible individuals:

- In mid-May 2005, CMS will be mailing a notice to low income subsidy (LIS) deemed population telling them that they will have drug coverage, when they can enroll, and answering basic questions.

- On May 25, 2005, SSA will start mailing the LIS application to 20 million Medicare beneficiaries who might be eligible for help. This mailing will end August 16.

- In mid-June 2005, CMS will send a notice to Supplemental Security Income-only individuals in the LIS deemed population.

- In mid-October 2005, CMS will assign full-benefit dual eligible individuals to prescription drug plans, and notify them of their assignment. (These individuals will be granted a "special enrollment period" to change plans if they do not believe the plan they have been auto-assigned into meets their medication needs).

- On January 1, 2006, the drug benefit begins for everyone enrolled in a plan, including those full benefit dual eligible individuals who were auto-enrolled.

- In May 2006, there will be a facilitated enrollment of the non-full dual LIS eligibles who have not enrolled with a Part D plan, with coverage effective June 1, 2006.

51. A separate plan to train caregivers and providers should be established in order to ensure a smoother transition. See response to number 56 regarding the CMS outreach and education campaign for Part D.

52. Encourage the development and use of educational templates and materials that can be localized. CMS' model marketing materials will allow organizations to put their "plan specific" contact information in bracketed areas within the materials. When a plan chooses to utilize CMS' model language "without modification," the plan will be subject to an abbreviated review period which will be determined by the type of material. Plans

that wish to "localize" their materials further do not have to utilize CMS' model language.

53. Closely regulate the PDP sponsors regarding the quality (i.e., readability) and content of the information they provide and their coordination with SPAPs. CMS will provide detailed marketing guidelines for Part D organizations and will work with the plans to ensure their coordination efforts with the SPAPs.

54. Do not rely on the use of the Internet as the sole or main means by which information is disseminated; additional forms of communication must be made available. The Internet will not be the only mechanism available for dissemination of Part D plan information. Section 1860D-1(b) of the Act allows for similar marketing rules for the drug benefit as those for MA. We intend to follow this guidance and promote marketing guidelines that are in line with those under the MA program. The MA program supports the use of Web sites, 800 numbers, mailings, e-mail and telemarketing for plan marketing. By allowing plans multiple routes for marketing, we believe that greater numbers of beneficiaries will be reached and thus enrolled in prescription drug plans.

55. Phase-in the education campaign beginning September 1, 2005, or as soon after finalization of the regulations as possible. CMS has already begun to phase-in an education and outreach campaign to overcome challenges and promote active, informed enrollment in Medicare prescription drug plans. CMS and its partners are carefully strategizing to not only educate a diverse audience of beneficiaries, their caregivers, and information intermediaries about coverage options under Medicare prescription drug plans, but motivate them to take action. The general timeline below illustrates the multi-phase approach CMS is using to implement its education and outreach activities:

Phase 1: Awareness - January 2005 – June 2005 CMS will conduct a general education and outreach campaign to explain the Medicare drug benefit at a high level. CMS will introduce the prescription drug plans and the extra help (LIS), while promoting 1-800-MEDICARE and www.medicare.gov as information sources. The campaign will encourage applications for the LIS as well as enrollment in Medicare prescription drug plans. Both CMS and the Social Security Administration (SSA) will send mailings to low income people with Medicare.

Phase 2: Decision - June 2005 – December 2005 CMS will conduct a national education and outreach campaign to inform people with Medicare of their drug plan options and let them know they can choose a Medicare prescription drug plan in fall 2005. The campaign will encourage people with Medicare to review their current prescription drug plans, choose a Medicare prescription drug plan and enroll, and to call 1-800-MEDICARE or visit www.medicare.gov to find out more information. CMS will mail a *Medicare & You 2006* handbook, containing localized drug plan and health plan comparison information, to all households of people with Medicare. CMS will also mail notices to people with Medicare and Medicaid information on their enrollment into a Medicare prescription drug plan. Training will be ongoing for local partners, states, and State Health Insurance Assistance Programs (SHIP) during this phase.

Phase 3: Urgency - January 2006 – May 2006 The focus of communications activities will be on people with Medicare that have not yet enrolled in a Medicare drug plan. CMS will develop a specialized plan for 1) identifying these people with Medicare; 2) ensuring that they are aware of the availability of Medicare prescription drug plans, the penalty associated with late enrollment, and the need to enroll in a Medicare prescription drug plan if they do not already have creditable drug coverage; and 3) overcoming any barriers that may be interfering with their enrolling in a Medicare prescription drug plan if they choose to do so.

56. PDP sponsors must be required to work with SPAPs on education and education materials. Require that CMS undertake an annual evaluation of access to drugs and of utilization of non-drug benefits, pre- and post-implementation and produce an annual report. We do not have the authority to require that Part D plans work with SPAPs on educational materials or activities, but we will encourage plans to work cooperatively with SPAPs to maximize the information available to beneficiaries. SPAPs may contact Part D plans to initiate discussion of information-sharing, education and co-branding opportunities. Part D plans will be required to work with SPAPs to facilitate benefit coordination, and CMS will be issuing standards that Part D plans must meet in this regard.

57. CMS should also make all data available to independent researchers, who can conduct their own studies of program effectiveness and make recommendations for programs improvements. CMS, depending on its authority to disseminate specific types of Part D data, agrees that any data that can be used to conduct studies to improve program effectiveness should be shared with independent research organizations. CMS has convened a workgroup to work on the issues and details of sharing data with outside interested parties. We do note, that the MMA contains fairly specific protections for some of the data collected by CMS under the Act. We will need to work within the confines of the statute and comply with the Privacy Rule in any data sharing.

58. Emphasize the importance of quality assurance (QA) and program evaluation by SPAPs by identifying key components and disseminating best practices. The final regulation specifies that each Part D sponsor must establish a drug utilization management program, quality assurance measures and systems, and a medication therapy management program that meet the requirements for these programs in Subpart D of the final regulation. While these Federal requirements do not apply to SPAPs, we would agree with this recommendation that it is important SPAPs have these types of quality improvement programs in place.

59. For effective QA, it is important to permit SPAPs access to the Medicare database. We do not believe it is necessary for an SPAP to have access to a Medicare database for QA purposes. As provided in section 423.32(b)(ii) of the Federal Regulations, we will require beneficiaries enrolling in or enrolled in a Part D plan to provide third party information. We encourage Part D plans and states to share data on shared enrollees, consistent with the HIPAA Privacy rule for sharing protected health information with another covered entity.

60. SPAPs should be encouraged to link with medical peer review groups to ensure scientific evaluation. The MMA has no statutory requirements related to the consultation of SPAPs with peer review groups.

61. HHS should make clear that assistance with the purchase of supplemental coverage includes assisting the individual with payment of premiums for basic, basic alternative or basic enhanced coverage. SPAPs will have the ability to coordinate benefits with Part D plans by paying beneficiary premiums for defined standard, actuarially equivalent standard, basic alternative, or enhanced alternative coverage, as well as by providing separate supplemental prescription drug benefits that "wrap around" a Part D plan. Part D plans will be required to coordinate benefits with SPAPs when SPAPs provide these separate supplemental benefits.

62. HHS should modify the regulation to specifically construe the non-discrimination provision of the statute as being satisfied by SPAP arrangements to determine the actuarial value of the benefit that it provides to enrollees, and to pay such amount to the PDP sponsor in which an SPAP beneficiary has enrolled. We will take this recommendation into account in the drafting of our guidance on requirements for effective coordination between SPAPs and Part D plans.

63. For SPAPs that provide supplemental coverage by picking up all or part of the enrollee's cost-sharing requirements, CMS should provide for at least the following three different options for coordinating with PDP sponsors: Federal Base Premiums, Fee-for-Service Cost Sharing and Customized Supplemental Coverage. Section 1860D-23 of the Act provides that Part D plans must coordinate with SPAPs for the payment of premiums and coverage, or for the payment of supplemental prescription benefits. In general, the options for coordination include payment of basic or supplemental premiums for Part D coverage or payment of cost-sharing balances as a secondary payer of claims (by providing wrap-around coverage). We envision that SPAPs can approach Part D plan sponsors to discuss the potential offering of supplemental Part D benefits, and may be able to negotiate directly with some Part D sponsors to provide separate ("customized") non-Part D wrap-around benefits. However, Part D plans will not be obligated to offer supplemental benefits and all supplemental benefits must be approved by CMS. Other suggestions for benefit coordination are welcome.

64. Establish a Centralized Data System to facilitate data exchange through a single entry point so that all involved parties have access to timely and accurate data needed for the "real-time" coordination of benefits. CMS is working closely with industry experts to establish a real-time coordination of benefits (COB) system by January 1, 2006 which will simplify the coordination process for all payers involved.

65. Establish a Long-term Technical Task Force – We recommend that a long-term technical task force of stakeholders be established as soon as possible to include representatives from all parties involved, including applicable standard-setting organizations such as the National Council for Prescription Drug

Programs (NCPDPs), to provide ongoing technical advice and recommendations. We agree and will evaluate options for ongoing technical consultation.

66. Part D Plans must be required to coordinate benefits with SPAPs. Section 1860D-23 places specific requirements on Part D plans to ensure that they effectively coordinate Part D benefits with SPAPs. We will issue guidance on required coordination activities and capabilities.

67. Part D plans should be required by CMS to inform the pharmacy on a claim response of any secondary coverage (e.g. SPAP), whether the claim is paid or denied. As required by statute at 1860D-23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage. We will take this recommendation under consideration in developing the Part D plan coordination requirements.

68. Require the Use of Standard ID Cards – CMS should require compliance with the NCPDP standard ID card format. As required by statute at 1860D-23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage. We will take this recommendation under consideration in developing the Part D plan coordination requirements.

69. E-prescribing should be implemented within the Part D Program. Title I of the MMA and our regulations require Part D plans to support final e-prescribing standards once they become effective. A notice of proposed rule-making was published in the Federal Register on February 2, 2005, outlining initial "foundation" standards that will be required at the outset of the Part D program. Further standards will be piloted and established no later than 2009.

70. Establish and Implement a Universal Payer ID – CMS should provide for the establishment of a universal payer or insurer ID for implementation with Part D in January 2006. As required by statute at 1860D-23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage. We will take this recommendation under consideration in developing the Part D plan coordination requirements.

71. User Fees for COB should not be imposed on or by SPAPs – Part D plans should not be able to impose user fees on SPAPs, nor vice versa, for coordinating benefits. Section 1860D-24(a)(3) of the Act permits CMS to impose user fees to defray the costs of Part D coordination of benefits, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. The MMA permits Part D plans to impose on SPAPs reasonable user fees related to the cost of coordination.

72. Require the Future Use of Payer-to-Payer Transmissions by PDP sponsors. As required by statute at 1860D-23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage. We will

take this recommendation under consideration in developing the Part D plan coordination requirements.

73. PDP sponsors should be required to participate in a retroactive recovery process. We assume from this recommendation that SPAPs want to be reimbursed for any funds it overpays when an SPAP beneficiary is later determined to be eligible for low-income subsidy assistance under Part D. If an SPAP, on behalf of the beneficiary, paid for the additional cost sharing during the time the individual was eligible for the low-income subsidy, the Part D sponsor offering the Part D plan must reimburse the SPAP for the excess cost-sharing. Section 42 CFR 423.800(c) provides that any excess premiums and cost sharing paid by organizations on behalf of the low-income subsidy eligible individual after the effective date of the individual's eligibility for a subsidy must be reimbursed by the Part D sponsor.

74. Part D Plans should be responsible for true-out-of-pocket (TrOOP) Tracking and should immediately credit SPAP enrollees for incurred costs. Part D plans will be fully responsible for TrOOP tracking. Our goal is to help develop a system for coordination of benefits that operates in as close to real-time as possible so that all TrOOP tracking is virtually instantaneous. We will provide further information on TrOOP tracking in our guidance on coordination requirements.

75. A Part D Plan knowing their member is also enrolled in an SPAP should automatically apply all incurred costs toward TrOOP. To the extent that an SPAP is a Part D enrollee's only source of wrap-around coverage, and the SPAP is qualified, Part D sponsors will apply the entire amount of claim costs not paid by the Part D plan (regardless of how much of that amount is paid by the SPAP) toward incurred costs.

76. Education Funds – CMS should dedicate necessary funds to educate beneficiaries, pharmacists and prescribers, or include this as appropriate in PDP sponsor requirements. CMS agrees and is undertaking extensive education campaigns and training sessions to educate beneficiaries and all Part D stakeholders on the Drug Benefit and the options available to beneficiaries.

77. Educational Content – CMS should determine minimum components of educational programs to prepare beneficiaries, pharmacists and providers to receive or efficiently deliver the benefit respectively. CMS agrees and is working with our provider education staff to develop materials for all providers, including pharmacists, for educational use.

78. Educational Program Delivery – CMS should determine which educational components are to be delivered through its control and which would be delivered by PDP sponsors or SPAPs. CMS has extensive and detailed education and outreach campaigns planned to inform beneficiaries of their Part D options. We will also assist SPAPs in adapting this information to ensure that their members understand the way that the new Part D plans coordinate with their SPAP benefit and supporting their members in making informed decisions about drug benefit plan options.

79. Program Development – Focus groups of beneficiaries, pharmacists and prescribers should be used to develop educational materials to ensure educational programs adequately prepare the respective group to efficiently receive or deliver the benefit. Education and outreach materials developed for beneficiaries will be thoroughly tested with the target audience.

80. Beneficiary Community-Based Organizations Education – PDP sponsors should be required to explain in plan materials how to coordinate benefits with other coverage, to make it clear when their plan should be used first and how other coverage may be used to cover out-of-pocket expenses or non covered purchases. We expect Part D plans to work with SPAPs on all coordination of benefit activities to ensure that beneficiaries are provided seamless care that is easily understandable. Requirements for coordination of benefits with other providers of prescription drug coverage are described under section 423.464 (e) of the final regulation.

81. To assess the success of the implementation of the coordination of Medicare Part D and SPAPs, system measures should be obtained at least quarterly, including a baseline measurement before implementation for involved SPAPs, pharmacists and patients. The establishment of system performance measures for the coordination of Part D plans with SPAPs is not a requirement of the MMA. However, we agree that CMS will need to evaluate the adequacy of the plan coordination guidelines we establish to ensure that these guidelines are helping in the successful coordination of benefits between the SPAPs and Part D plans. As required by statute at section 1860D-23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage. We welcome all comments and recommendations by the State Pharmaceutical Transition Commission regarding the Part D plan coordination requirements.