July 11, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Medicare and Medicaid Coordination Office
Attn: CMS-5507-NC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-5507-NC, Medicare and Medicaid Programs: Opportunities for Alignment Under Medicaid and Medicare

By electronic submission to www.regulations.gov

To whom it may concern:

The undersigned beneficiary advocacy organizations submit the following comments on the above-referenced Request for Information. We thank CMS for its work attempting to identify areas within Medicare and Medicaid where differences exist in beneficiary rights, program coverage, or regulatory requirements. We appreciate the opportunity to comment on the document and to provide ongoing input as CMS works to improve the beneficiary experience with these programs. Our comments comprise overarching principles, identification of our priorities for CMS action, specific comments on and proposed solutions for various components discussed in the Request for Information, and identification of issues missing from the document.

We understand the primary concerns addressed in the document to be threefold:

1. **Improving access to services for dual eligibles:** Identifying areas where differences in the programs create difficulties for beneficiaries in accessing the coverage and/or services to which they are entitled under one or both programs.

2. **Eliminating conflicting program requirements that impair private plans or providers from easily participating in both programs:** Identifying irreconcilable conflicts that preclude a single entity from offering services under both programs.

3. **Reducing or eliminating perverse incentives to shift costs from one program to the other:** Identifying areas where program design or coverage differences provide incentives to each program to try to shift costs to the other.

OVERARCHING PRINCIPLES

Beneficiaries are entitled to all medically necessary services covered by both programs. Solutions to coverage differences and regulatory conflicts should be designed to ensure that

beneficiaries receive all services and all due process and appeals rights to which they are entitled under both programs.

Medicare coverage should be maximized to beneficiaries' advantage not to their detriment. Medicare is the primary payer for most coverage for dual eligibles. Where Medicare coverage is used to access services, the primary concern is that cost-sharing protections under Medicaid are not violated. If a beneficiary accesses services under Medicaid, rather than Medicare, payment for those services may be subject to recovery from the estate of the deceased beneficiary. It is, therefore, to the beneficiary's advantage to maximize Medicare coverage. However, if the beneficiary is not able to access services through Medicare when needed (i.e. the beneficiary is awaiting a decision on an appeal), the beneficiary should be able to access these services through Medicaid while awaiting a determination from Medicare.

Differences are not always conflicts and do not necessarily need reconciling. Where, for example, Medicare and Medicaid have different coverage rules for a service, often all that is needed is an easy way for beneficiaries to navigate the difference, so as to get maximum benefit from both programs. In some instances, prior authorization under either or both programs will provide a sufficient solution, at least in the short term.

More frequent and improved data sharing between the States and CMS will alleviate some access difficulties identified. Although not explicitly discussed in this document, except with respect to recertification, enrollment in the Medicare Savings Programs and the Medicare Part D Low-Income Subsidy are different though not precisely conflicting. We know from experience over the past several years that real time or at least daily data sharing among the various entities (States, CMS, SSA, drug plans) that need information improves access for duals to essential health care services. More timely data sharing between states, CMS, and SSA could also speed activation of Medicare Savings Programs benefits after a state has determined a beneficiary to be eligible.

PRIORITIES

As CMS pursues its agenda of aligning Medicare and Medicaid in such a way as to align benefits and incentives and improve access for beneficiaries under both programs, we encourage CMS to keep these priorities in mind:

1.) Streamline access to programs so more people can establish dual eligibility and obtain access to benefits quickly,
2.) Fix problems with existing program and delivery models so that dual eligibles get more seamless care,
3.) Innovate in ways that improve beneficiaries access to care and include strong beneficiary protections, and
4.) Maintain a transparent process that allows for meaningful beneficiary input.

The overarching principles identified above apply to most, if not all, of the situations addressed in the individual segments of the Request for Information.

We commend CMS for its commitment to improving dual eligibles experience with the Medicare and Medicaid programs. We look forward to continuing to work with you on this and other initiatives. Please find attached comments to the specific issues addressed in the Request for Information. We have also attached additional supportive documents if references are not easily available electronically. If you have questions, please contact Marc Steinberg (msteinberg@familiesusa.org) or Michealle Gady (mgady@familiesusa.org) (202-628-3030) at Families USA, who can convey any inquiries to the other signers of these comments.

Very truly yours,

Alzheimer's Association
Center for Medicare Advocacy, Inc.
Families USA
Medicare Rights Center
National Health Law Program
National Senior Citizens Law Center

SPECIFIC COMMENTS

We first note that throughout the RFI, CMS sometimes attributes a difference or conflict only to MA, SNPs, or FFS, when the issue in fact has broad applicability. For example, on page 28202, Coordinated Care, Field 10, SNP – Internal grievances and appeals, we note that these differences apply to fee-for-service, as well as in managed care. The same is true for seamless delivery of services. We recommend that CMS be mindful of the broad applicability of many of these issues and not limit its focus to resolving differences only in one part of the program when it should be resolved across the program.

1.) Coordinated Care

Dual eligible beneficiaries are often among the sickest and most vulnerable patients in the health care system. They are also among the most costly patients. However, neither Medicare nor Medicaid is responsible for coordinating care and benefits. This lack of coordination and differences between the two programs means that this population is least likely to have access to coordinated care and instead find themselves in a highly fragmented system. As a result, dual eligible individuals often receive duplicative or unnecessary tests and treatments and often encounter problems accessing the care that they need in the setting they need.

Over the years, some initiatives have tried to improve coordination between Medicare and Medicaid, with mixed success. These include Medicare Advantage Special Needs Plans (SNPs) and the Program of All-Inclusive Care for the Elderly (PACE). While the PACE program has delivered high quality, fully integrated services, the rules and necessary infrastructure have made it difficult for this program to expand to more people, and as a result, few dual eligibles are

enrolled in PACE programs. Medicare Advantage Dual Eligible Special Needs Plans (D-SNPs) were created with the intent of coordinating care for dual eligible beneficiaries thereby improving the quality of their care and lowering costs. Unfortunately, few SNPs have achieved this goal. Managed care does not necessarily mean coordinated care and in the case of Medicare Advantage plans, it has not lead to cost savings for Medicare.

With that in mind, we are concerned that the general focus of the Care Coordination section in the RFI focuses almost exclusively on private managed care. As CMS moves forward with the alignment initiative and its other efforts to improve care coordination for dual eligibles, we strongly recommend that CMS take a broader approach to care coordination. Where program differences and regulatory conflicts affect managed care plans, they will also affect other care coordination models (for example, PACE and primary care case management) and, therefore, must be addressed through that broad lens.

As CMS pursues its recently announced (July 8, 2011) demonstration to test financial models to integrate care for dual eligibles, many of the issues raised in this RFI will need to be addressed. CMS will need to incorporate strong quality measurements. Experience with the Medicare Advantage program thus far, particularly Special Needs Plans, has resulted in little meaningful information about quality measures that are important to this population, including the quality of the care coordination model that the plan uses. We also strongly recommend CMS include robust consumer protections in all demonstrations, including maintaining freedom of choice of provider and due process rights. We urge CMS not to prioritize simplicity for plans over the need for rigorous consumer protections. Mandatory enrollment or passive enrollment schemes create problems for beneficiaries, particularly when they are already enrolled in coverage and have an on-going relationship with a provider (as we discuss repeatedly in these comments below). Finally, we urge CMS to ensure an open and transparent process as these state demonstrations develop, both at the state and federal level, to ensure meaningful and active participation by consumers and their representatives.

<u>Field 1: Coordinated Care – Enrollment and Field 4: Coordinated Care – Seamless conversion:</u>

We believe that the RFI confuses the need to create delivery system infrastructure that fosters care coordination (which we support) with the need to forcefully promote enrollment into care coordination programs, and more specifically, private managed care coordination programs.

We are concerned that language in the "Enrollment" (page 28200) and "Seamless conversion" (page 28201) fields implies that CMS believes that low enrollment into dual eligible Special Needs Plans or other care coordination programs can only be resolved with mandatory enrollment or auto-enrollment. Mandatory or auto-enrollment schemes can be very disruptive to a beneficiary's care, which should never happen. While we support and see the need for improved coordinated care models, we believe that the Medicare, and where applicable Medicaid, freedom of choice of provider provisions should be maintained. Care coordination models should utilize a variety of enrollment approaches.

Rather than taking a narrow approach to increasing enrollment in care coordination models, we recommend CMS consider all available options for increasing enrollment, including:

- Addressing limitations that prevent PACE programs from expanding to serve more dual eligibles,
- Better dissemination about options for care, such as PACE, Primary Care Medical Homes, and other models to consumers,
- Commitment to active consumer choice as the primary method of enrollment into care coordination programs. We recognize that some situations warrant auto-enrollment or some similar approach, such as when no active choice by the beneficiary means the beneficiary will not have coverage. However, in such situations, beneficiaries must always have access to an easy, meaningful opt-out process.

Field 2: Coordinated Care – Options:

We reiterate that private managed care is one limited vehicle for care coordination. In fact, the D-SNPs have not documented significant results regarding care coordination. Consumers have not had any concrete coordination "service" to request or demand – indeed, neither consumers nor researchers have even been able to obtain models of care coordination for most SNPs.[1] CMS should be equally willing to consider other methods for coordinating care, such as primary care case management programs (PCCM). To the extent the RFI promotes care coordination structures, it should do so neutrally as between diverse care coordination systems, including PCCM, PACE, medical homes, ACOs, MA plans, SNPs, etc.

Field 3: Coordinated Care – MA Cost Sharing Information In Standard Summary of Benefits:

To solve the problems identified in this field, we recommend (as we have done previously) that CMS produce separate notices for dual eligibles regarding cost-sharing. This should be done for both MA plan and FFS enrollees, and should be tailored to each category of dual eligible (e.g. full Medicaid, full Medicaid with QMB, QMB only, SLMB/QI). The standard summary of benefits is already confusing, and adding addenda to it only increases confusion for beneficiaries.

We also note that while states are required to pay for Medicare cost-sharing for QMBs and full benefit dual eligible beneficiaries in MA plans, states do not consistently implement this requirement. For example, the State of Florida has a written policy to not pay such cost-sharing for beneficiaries enrolled in MA plans.[2] (See also our discussion of cost-sharing, below).

Field 4: Coordinated Care – MA—Seamless Conversion:

We believe this field contains a fundamental misstatement of law. The RFI asserts that Medicare statute or regulation permits seamless conversion with the option to opt-out, but it does not provide any citation to a statute or regulation in support of this contention. We believe such a statute or regulation does not exist, and such a policy, if it existed, would violate Medicare's freedom of choice of provider rules. Moreover, seamless conversion is not necessarily seamless

[1] See MedPAC Report to the Congress, *Medicare and the Health Care Delivery System*, June 2011, Chapter 5.
[2] Florida Medicaid Provider General Handbook, page 4-2, available at https://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/GH_09_090204_Provider_General_Hdbk_ver1.3.pdf.pdf

to the beneficiary. The MA plan into which the Medicare beneficiary is enrolled may not include the beneficiary's current Medicaid providers and enrollment could result in disruptions in continuity of care that can be especially devastating to frail elders with limited income. Given D-SNPs often-dismal history of ensuring adequate networks of Medicaid providers, automatic enrollment into D-SNPs could be quite detrimental to beneficiaries. We urge CMS to be particularly mindful of these problems as it implements its proposal to allow flexibility in enrollment procedures in the financial model demonstration announced July 8, 2011.

Field 5: Coordinated Care – PACE – External Appeals:

It is unclear why this field is limited to PACE. Accessing the different external appeals processes will be necessary regardless of whether or what kind of care coordination program a beneficiary participates in. While the appeals processes between the two programs may be different, they are not necessarily in conflict. We urge CMS to ensure that beneficiaries maintain their rights under both programs. A single, streamlined appeals process may not be in the best interest of the beneficiary, particularly when an alternative solution is to provide the beneficiary with assistance in navigating the two systems, as is done in the PACE program. We urge CMS to be particularly mindful of this given its proposal to create a single, unified appeals process in the financial model demonstration announced July 8, 2011.

Field 6: Coordinated Care – Low Income Medicare Beneficiaries at Risk of Declining to Point of Qualifying for Medicaid:

Given that the focus of this section is predominantly managed care, this field implies that although Medicare FFS does not have the flexibility to help prevent people from declining to the point of qualifying for Medicaid, MA plans somehow do and have been effective in doing so. We do not consider either implication to be the case.

To address this problem, we recommend that CMS pursue the following policies either administratively or legislatively:

- Medicaid paying for cost-sharing for QMBs (who are not full duals) at the full Medicare rate, which would improve access to needed services and prevent beneficiaries from declining, becoming impoverished, and qualifying for full benefits under Medicaid,
- Eliminating the inappropriate use of the improvement standard in Medicare would improve access to services that could help prevent decline, and
- Changing the Medicare homebound standard would also help prevent decline.

Field 7: Coordinated Care – Special Needs Plans – Current Contracting Issues:

While we recognize there may be differences in contracting requirements under Medicare and Medicaid, including different reporting requirements, we do not believe this necessarily means all of the differences conflict. We encourage you to be specific as to what differences create irreconcilable conflicts. For example, if one program merely requires more reporting than the other, this is a difference, but nothing prevents a provider/contractor from meeting both standards. We believe the unification of standards should not prioritize simplicity over robust

standards. States, for example, may wish to set more rigorous standards on quality or accountability for their Medicaid contracts than CMS sets in its Medicare contracts. As long as federal rules are a floor, and not a ceiling, there is no conflict.

Field 8: Coordinated Care – Managed Care SNP – Enrollment Requirements:

We agree that the different enrollment procedures in Medicaid and Medicare can be confusing and burdensome to beneficiaries. However, we caution that any attempt to simplify enrollment into care coordination programs – not just managed care programs – must be done so with the beneficiaries and their needs as the focus. The beneficiaries must retain all of their rights and protections that currently exist under both programs, including access to opt-out procedures and special enrollment periods. Also, mandatory or auto-enrollment procedures should not be seen as the default option to ease the administrative burden.

When undertaking new enrollment initiatives, both states and CMS should improve communications with those serving beneficiaries, such as State Health Insurance and Assistance Programs (SHIPs) and Area Agencies on Aging (AAAs). Counselors and these organizations can provide the personalized, unbiased advice that beneficiaries need, but their advice is only as good as the information the counseling organizations receive.

Field 9: Coordinated Care – SNP- Future Contracting Issues:

This field does not address a program alignment problem or conflict. This merely reflects that SNPs dislike that they are required to contract with the State, but that the State may contract selectively. This issue should not be addressed in this alignment RFI. Regardless, we think states should retain full authority to decide whether they will contract with dual eligible SNPs and if so which ones. If a state determines that particular SNPs, or all SNPs, do not meet its standards for serving dual eligibles, the state should not be required to contract.

To the extent that states that do contract with D-SNPs, CMS should establish minimum standards for quality and accountability, including ensuring adequate networks of dual providers.

Field 10: Coordinated Care – SNP – Internal Grievances and Appeals:

As stated previously, it is not clear why this field is applied only to SNPs. We consider this to be a significant issue for any alternative delivery system, including new delivery system models such as ACOs. In models such as ACOs, there is a potential for providers to limit access to medically necessary care in an effort to lower expenditures, among other reasons. Therefore, it will be necessary for beneficiaries to have access to an internal appeals/grievance process. As such, the differences between the programs' appeals/grievance requirements will need to be addressed. The core elements to be addressed are how well beneficiaries understand the processes available to them, how expeditiously the processes work to help the beneficiaries, and whether they are able to receive aid pending their appeal. We comment further on these elements in the appeals section.

Field 11: Coordinated Care – SNP – Marketing

We reiterate our prior point that marketing issues are not limited to SNPs or managed care plans in general, but will be an issue that must be addressed with all care coordination models.

We also again note that differences in policy do not necessarily imply conflicts. Where one program has stricter marketing rules than the other (and where a plan provides both services), the stricter rules should apply, which eliminates any potential conflict. Of course, we understand that similar requirements might be simpler to administer, but simplicity should not be a higher priority than these important consumer protections.

We also note that some of the marketing abuses seen in the Medicare Advantage market (for example, agents and brokers signing beneficiaries up for inappropriate plans in pursuit of lucrative commissions) are minimized in some states' Medicaid programs by the use of third-party enrollment brokers rather than individual agents and brokers. These enrollment brokers do not have an incentive to enroll beneficiaries in any particular plan. Such a model could be helpful in Medicare.

Dual eligibles who have limited proficiency in English need consistent access to information about both programs. Medicare requirements for Part C and D set a threshold for translation of marketing documents at 5% of the general population in the service area of the plan. We note that the RFI incorrectly states that the requirement is 10% of the plan's service area. The 5% threshold is only for enumerated marketing documents and does not address other communications such as notices concerning appeals.

To date, CMS has set a threshold of 10% of the general population for its own obligations to translate "vital" documents. CMS call centers and Part C and D plans are required to offer interpreter services in all languages. State Medicaid programs vary widely in translation and interpretation requirements. The lack of consistency across programs and the incomplete coverage of translation requirements create confusion among LEP beneficiaries and leave them vulnerable to marketing abuses.

To address these problems, we recommend that CMS:

- Set translation thresholds for Part C and D plans that, besides looking at percentages of the general population, also take into account the absolute number of LEP members in a plan speaking a particular non-English language,
- Expand and accelerate efforts to translate model documents in order to ease the burden on plans and encourage compliance,
- Extend translation requirements beyond the limited number of marketing documents now covered and include key items like appeal notices,
- Require of itself a more expansive responsibility for translation of its own documents. (We recognize that the agency has, in fact, begun to translate more of its own documents but the agency also should make a formal commitment to broaden its translation responsibilities.),

- Require state Medicaid agencies to set translation and interpretation standards at least as rigorous as those set by CMS and that are consistent with Title VI of the Civil Rights Act. CMS should monitor state compliance,
- Require that, in addition to marketing thresholds set by regulations, plans that choose to market to individuals in any non-English language must provide key documents, such as Evidence of Coverage and application forms, to those individuals in their language before enrollment, and
- Work with the states to develop a set of core communications in many languages that explain to dual eligibles how to use the two programs together and what their rights are within each program, including their rights to language assistance.

Field 13: Coordinated Care – SNP – Seamless Delivery of Services:

This is a critical dual eligible issue with applicability far beyond SNPs. Our comments here address seamless delivery of services between Medicare and Medicaid broadly and are not limited to SNPs.

As we have previously explained, we approach this issue with a fundamental principle in mind: every enrollee who has Medicare and Medicaid is entitled to the full benefits of *each* program, irrespective of their status as a dual. Therefore, no dual eligible should receive less Medicare services because she is enrolled in Medicaid or less Medicaid services because she is enrolled in Medicare. There is no good legal or policy basis for any other outcome.

The critical need for consumers is to ensure they access the full scope of their Medicare benefit. Over-reliance on Medicaid may result in consumers being subject to Medicaid Estate Recovery provisions that would not have affected them if Medicare had appropriately paid for their services.

When a beneficiary must access coverage through Medicaid for a service that is also covered by Medicare, the fundamental problem that consumers face in accessing that benefit is the requirement that they must demonstrate that they cannot access coverage under Medicare (i.e. Medicare denial). We believe that a well coordinated system for duals would operate under a "pay and chase" type of system. Under this approach, Medicaid covers the service and the consumer immediately accesses the service, but pursues either Medicare coverage or a denial. Some states have facilitated this approach through prior authorization systems to reassure service providers. Under such an approach, the provider is given an assurance that if Medicare does not pay, Medicaid will. However, it is important to note that once Medicaid has paid, there must truly be an active effort to assure Medicare pays its share, if appropriate, to avoid the Medicaid Estate Recovery problem mentioned earlier.

Of course, this process would be aided by making expansive coverage adjustments to both programs to forge alignment. For example, the Medicare eligibility requirements to access services, such as home health care, or supplies, such as wheelchairs, apply anachronistic needs requirements that patently contradict the goals of community integration and person-centeredness for the dual eligible population.

2.) Fee for Service Benefits

CMS and States should promote, to the maximum extent possible, dual participation in both Medicare and Medicaid by providers who serve dual eligibles. Providers participating in both programs will be familiar with both programs' coverage rules and will be in the best position to help beneficiaries get full coverage of services they need and to which they are entitled.

Field 2: FFS Benefits – DME:

Although Medicaid regulations address DME only in the context of home health benefits, in fact, Medicaid DME coverage is not limited to items for use in the home, reflecting Medicaid's purpose as being "to help. . . individuals attain or retain capability for independence or self care" (42 U.S.C. § 1396-1). Medicaid's more expansive definition of medical necessity has implications in areas beyond DME, but its effects are often brightest with respect to the availability of coverage for wheelchairs and for other equipment that might not be covered by Medicare at all. (See discussion of Connecticut Department of Social Services Medical Assistance Program Provider Bulletin on Definition of and determination of Medical Necessity for Durable Medical Equipment (Nov. 2003))[3]

The access issue for duals arises from states' imposing a requirement that duals (requirements arising from the states' obligations to seek payment from all liable third parties and for Medicaid payment to be payment of last resort) present a Medicare coverage determination before the state will pay its share. A Medicare coverage determination is made only when a service or supply is received. If the DME item is expensive – a wheelchair, for example – the dual eligible is unlikely to be able to shoulder the financial liability in the event coverage is denied.

Dual eligibles who were Medicaid-only first are those most likely to see disruptions in care because of these overlaps and conflicts. Many have had established channels for getting the DME that they need but when they become dually eligible find that suddenly they face barriers and delays because of the need to route DME orders through Medicare first.

Several states have addressed this issue by creating a process that allows a beneficiary to get prior authorization of Medicaid coverage, to assure the provider of the item or supplies that there will be a source of payment. For example, Connecticut's Medicaid statute provides that Medicaid covered durable medical equipment "shall not be denied to a recipient on the basis that a Medicare coverage determination has not been made prior to the submission of request for preauthorization to the Commissioner."[4] As applied to a DME item requiring prior authorization, the Connecticut process is straightforward. The individual first requests prior authorization from the state Medicaid agency. If approved, the provider provides the equipment to the individual and then bills Medicare. If Medicare pays, the transaction is complete. If Medicare does not pay, the provider then bills the Connecticut Medicaid agency, which has already agreed to pay through the prior authorization process. In this way, providers have the assurance that they will get paid, although they do not have certainty about which agency will pay and at what rate.

[3] The bulletin is attached to this document.
[4] C.G.S.A. §17b-281a

Such a process could be adopted by all states and used in all situations where states currently will not evaluate or provide coverage prior to receiving a Medicare determination.

A Medicare prior authorization process could improve these situations, as well. Currently, the Medicare Integrity Manual includes a prior approval procedure for Medicare coverage of certain DME but the availability of the procedure is limited. The DME must be a customized and "not inexpensive" item.[5] In practice it is mostly limited to customized wheelchairs and not widely used. A broader and simpler Medicare process could be helpful.

Individuals moving from Medicaid-only to dual eligibility should have transition rights that guarantee continued access for a reasonable period of time to all goods and services that they were receiving through Medicaid. These transition rights would be similar to those available in Medicare Part D for individuals stabilized on a drug regime. For DME, a six month transition period would also be appropriate, allowing time for individuals and their treating professionals to adjust to new procedures and requirements.

A final point and one that is significant for dual eligibles is that Medicaid prohibits "exclusive lists" of durable medical equipment that is coverable by the program. In Medicaid, DME is not specifically defined. It is covered as part of the home health benefit (42 CFR 440.70(b)(3)) but is not restricted to the home[6] and may also be covered under other Medicaid benefits such as rehabilitative services (42 CFR 440.130(d)). Further, CMS has informed states that they may not use an exclusive list of approved equipment, but must provide an opportunity for beneficiaries and providers to show that equipment not on the list satisfies the criteria for coverage.[7]

Field 3: FFS Benefits – Home Health:

Medicaid requires neither that the beneficiary be "homebound" to receive services, nor that the services be "skilled," both of which are statutory requirements for Medicare home health coverage. In fact, Medicaid's use of a "homebound" requirement is prohibited by CMS' interpretation of requirements of the decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999).[8] The Medicaid home health regulations at 42 C.F.R. § 440.70 refer to coverage for "nursing services" not "skilled nursing services." Also, Medicare coverage too often is denied because the individual is "not improving," a standard that appears nowhere in Medicare statute or regulation. Advocates understand that "improvement" is beginning to show up in Medicaid as well.

To address these problems, we recommend that CMS:

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[5] Medicare Program Integrity Manual, Ch. 5 at 5.16

[6] State Medicaid Director letter, July 25, 2000, available at http://www.cms.gov/SMDL/SMD/itemdetail.asp?filterType=dual,keyword&filterValue=olmstead&filterByDID=0&sortByDID=1&sortOrder=descending&itemID=CMS063799&intNumPerPage=10

[7] State Medicaid Director Letter, September 4, 1998, available at http://www.cms.gov/SMDL/SMD/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS1186338&intNumPerPage=10

[8] Letter from the Center for Medicaid and State Operations to State Medicaid Directors (July 25, 2000), available at http://www.cms.hhs.gov/smdl/downloads/smd072500b.pdf.

- Work toward elimination of statutory requirements in Medicare that beneficiaries be homebound and in need of skilled services to qualify for Medicare home health coverage,
- Eliminate all references in any policy manuals and provider education materials to the need for a beneficiary to "improve" in order to receive services under Medicare and direct states that such requirements are inconsistent with the dictates of *Olmstead* and, therefore, impermissible,
- Identify all states currently using "homebound" or "skilled service" or both requirements in their home health coverage and clearly inform those states that such policies violate Medicaid law, and
- Identify and communicate to the states best practices for ensuring that:
    - beneficiaries get all the Medicare coverage to which they are entitled (including, e.g., appeals of denials of determinations that the beneficiary is not homebound),
    - beneficiaries are able to get Medicaid coverage easily pending a Medicare appeal, and
    - full Medicaid coverage is easily available as a wrap around to the Medicare coverage that is available.

Field 4: FFS Benefits – Nursing Homes – Hospital Transfers

Medicare's payment to skilled nursing facilities includes a substantial portion for staffing, but CMS does not require SNFs to allocate that money to staff. If SNFs were better staffed, they would be better able to address conditions that arise that now lead to hospitalizations. Since nearly all SNFs are also certified as Medicaid nursing facilities (NFs), better staffing would inure to the benefit of all residents of the facilities, most of who are dually eligible.

In addition to the transfer issues identified by CMS, a concern related to nursing homes is the difference in rehabilitative services that many dual eligibles often receive in SNFs, depending on whether their stay is being paid for by Medicare or Medicaid. Although SNFs are supposed to provide the same rehabilitative services regardless of payment, the reality for many dual eligibles is that the amount and scope of services drops off considerably once Medicare payment stops and lower Medicaid payments begin. These drops in service are independent of whether there has been a change in medical need for those services.

To address these problems, CMS should:

- Audit SNF payments to facilities to ensure that money designated for staff is directed to staff,
- Educate SNF/NF staff about the possibility and process of re-instating Medicare coverage that has ended within the 100 day coverage period in situations where the resident's condition is such that Medicare coverage is appropriate. This is likely to be true where a resident's condition may otherwise require hospitalization.
- Eliminate all references in any policy manuals and provider education materials to the need for a beneficiary to "improve" in order to receive services under Medicare. Such a step will promote maximum Medicare coverage, including access to therapies that may allow an individual to leave the facility and move into the community. CMS should also

direct states that such requirements are inconsistent with the dictates of *Olmstead* and, therefore, impermissible.

- Along with states, vigorously enforce statutory requirements for provision of rehabilitation services. Medicaid reimbursement rates also should be examined to determine whether they, in fact, support provision of required rehabilitative services.
- Investigate inappropriate use of observation status by hospitals, which can deprive beneficiaries of possible Medicare coverage of subsequent Skilled Nursing Facility stays.

Field 5: FFS Benefits – Skilled Therapies:

Continuity of care with skilled services can make a significant difference in health outcomes and Medicaid credentialing requirements can create barriers to that continuity.

One partial response to this concern could be a CMS regulation requiring credentialing flexibility by Medicaid agencies for skilled services for dual eligibles. Specifically, if a dual eligible has begun skilled therapies with a Medicare-only provider and needs continued therapy that is covered by Medicaid but no longer covered by Medicare, and if that provider is willing to accept Medicaid rates for that dual eligible, the state Medicaid program must establish procedures to process payment to that provider without that provider needing to enroll in Medicaid or meet Medicaid credentialing requirements. The concept would be similar to that for payment of Medicare co-pays for QMBs by state Medicaid agencies, even if the provider is not enrolled in the state Medicaid program.[9]

3.) Prescription Drugs

There are issues beyond enrollment in benefits, which are not addressed in the RFI, that may be problematic for dual eligibles and potentially create barriers to prescription drug access. Some of these relate to when the individual transitions from the Medicaid drug benefit to the Medicare drug benefit. Because of the different coverage rules, this transition can cause interruptions in access or require individuals to change drug regimes. For example, Medicare drug coverage is wrought with utilization management requirements such as prior authorization. Each Medicaid program may require their own utilization management rules that are different than those required under a Medicare drug plan. In order to prevent interruptions in care, CMS should analyze the current prescription drug transition fill policy that exists under Medicare and Medicaid to ensure that dual eligibles new to Medicare are able to access their current drugs while they are transitioning to new ones or while there is a coverage determination, appeal, or exception request pending.

Other problems relating to prescription drugs are the result in differences in coverage rules and benefit structures that may lead to confusion once an individual is already a dual-eligible. Given the structural differences in Medicare and Medicaid drug coverage, duals may run into access barriers because of the difficulty in determining Medicaid's responsibility to provide primary coverage or wrap around coverage based on which part of the Medicare program is responsible for payments. Specifically, some drugs are covered under Medicare Part B, while others are

[9] In most states, the mechanisms for QMB payments do not work well and need improvement. See our discussion re Cost-sharing-Balance Billing of QMB. Improved systems could be applied both here and with QMBs.

covered under Medicare Part D. The coverage rules, appeals processes, and cost-sharing requirements are different under the different parts. If a drug is covered under Part B, Medicare acts as primary payer and Medicaid as secondary payer. If drugs are covered under Part D, dual-eligibles receive subsidized coverage through the Extra Help program and Medicaid does not act as the secondary payer, except in limited circumstance. Given the different coverage rules, it can be difficult for the beneficiary or the State to determine which program is responsible for covering the drug.

In cases where Medicaid provides more expansive drug coverage than Medicare, it is important that duals are able to access Medicaid coverage. One example is access to certain off-label drugs. Medicaid programs have the flexibility to cover off-label prescriptions and many states do so. The federal Medicaid law that addresses off-label use provides that a "state may exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication."[10] If states offer prescription drug coverage, they must not put restrictions on off-label use beyond those stipulated in the federal law—but they may grant more generous coverage than the federal statute requires. However, such flexibility for coverage does not exist under Medicare, which contains a more restrictive off-label coverage standard. Specifically, Medicare will not cover a drug prescribed for off –label use unless such use is favorably listed in statutorily identified compendia or, in the case of drugs used to treat cancer, supported by peer reviewed medical literature. For this reason, some duals rely on Medicaid to access prescription drugs that they would otherwise be unable to afford. Such access must be maintained.

Lastly, CMS has promulgated a new rule under Medicare requiring that, in the future, denial notices for drugs must be issued at the pharmacy; however, these notice requirements do not apply to the Medicaid program. Ideally, CMS should require that all Medicaid and Medicare plans issue individually tailored, electronically generated notices at the pharmacy whenever drugs are denied. However, as a first step, Medicaid pharmacy notice requirements should be brought into line with those that exist under Medicare. (See attached letter to Administrator Berwick, November 22, 2010)

4.) Cost-Sharing

Field 1: Cost-sharing – Crossover Claims:

The issues raised in this field are largely responsible for eviscerating the QMB benefit. Because states are allowed to limit Medicare co-payments to the Medicaid rate (which in many cases means that a provider gets nothing beyond what Medicare pays), Medicare providers are unwilling to care for QMB patients, or else balance bill them in violation of the law. The overly complex and frequently dysfunctional payment procedures used by states add to the problem. Advocates report that QMBs face the greatest access problems with primary care physicians and specialists.

To address these problems, CMS should:

[10] 42 U.S.C. §1396r-8(d)(1)(B)(i) (2007).

- Support a change in the statutory provision allowing co-payments for QMBs to be limited to the Medicaid rate. QMBs will not get full access to providers unless their providers receive the same payments for serving QMBs that they receive for serving other Medicare beneficiaries.
- Require states to establish better mechanisms to pay all providers for QMBs and prohibit systems that impose unnecessary barriers to processing claims. CMS should monitor state compliance and provide states with technical assistance to improve their payment systems.
- CMS should consider broader changes, including a larger federal role, that could decrease the current complexity of the program and improve access.

Field 2: Cost-sharing – Balance Billing for QMB:

QMBs are excused, by statute, from both Medicare cost-sharing and from balance billing (billing above the Medicare-approved rate) by providers. Several issues arise related to this protection, in addition to those identified in the document.

First, QMBs themselves, many of their providers, and MA plans serving duals do not seem to understand the how the benefit works. The benefit allows QMBs to seek services from Medicare-only providers or providers enrolled in both Medicare and Medicaid and not be billed at all for those services.

Second, QMBs may not have cards identifying them as QMBs. If they are also full dual eligibles, their Medicaid card may only identify them as full Medicaid, a status that limits them to using Medicaid providers. If they are QMB-only, they may not think to tell this to the provider, or the card may look like a regular Medicaid card with QMB information not clear, or the provider may not be familiar with the program.

Third, Medicare-only providers may not know that they are prohibited from billing QMBs and/or they may not know how to bill the State for cost-sharing. Or they may not want to serve QMBs because the State's Medicaid rate is below the Medicare approved-amount and the state will only pay up to the Medicaid rate.

Fourth, the State may not have an easy system for a non-Medicaid enrolled provider to bill for QMB cost-sharing.

To address these issues, CMS should:

- Conduct an intensive educational campaign to providers, beneficiaries, MA plans, and those serving beneficiaries such as SHIP counselors, to help them understand the QMB benefit,
- Identify and promote best practices for receiving claims from Medicare-only providers for QMBs
- Direct states to issue identification cards to QMB-only individuals and to include an identifying code on the Medicaid cards of QMBs with full Medicaid, so that beneficiaries can more easily receive Medicare services from non-Medicaid providers,

- Consider creating an identifying code that would flag Medicare claims for QMBs as being eligible for cross-over status, so the claims are automatically sent to Medicaid for payment. Payment notices going to providers from both Medicare and Medicaid should remind the provider that the patient may not be balance billed,
- Promote policies, including statutory changes, that require providers be paid at the full Medicare rate for their services, and
- Along with states, enforce the balance billing protections by imposing sanctions on providers who willfully violate the balance billing prohibitions. Sanctions should also be imposed on MA plans that do not honor Medicaid cost-sharing rules for their dual eligibles.

5.) Enrollment

Field 1: Enrollment – Medicare Part A Buy-in:

There are several reasons why having Medicare Part A coverage is advantageous to a dual eligible, including: 1) Part A is necessary for QMB status and QMB status, by paying Medicare premiums and cost-sharing, theoretically, allows a beneficiary to see Medicare-only physicians and other providers, 2) Hospital coverage is likely to be more extensive than under Medicaid (which varies from state to state), 3) Rehabilitation services are also likely to be more robust under Medicare than under Medicaid, and 4) Payments for Medicare services are not subject to recovery from the estate of the deceased beneficiary.

CMS states that 35 States and the District of Columbia have elected to buy-in to Part A for non-QMBs. It does not mention the convoluted process for QMBs needing to have Medicaid pay for their Part A in both "buy-in" and non-buy-in states. Where states have buy-in agreements with CMS, they can enroll their duals into Part A at any time of the year, and without paying a late enrollment penalty for those who did not enroll during their initial enrollment period. In states without a buy-in agreement, individuals are limited to the General Enrollment Period from January through March each year with their benefits beginning July 1 of the year they enroll. This circumstance can result in individuals being denied QMB benefits for 15 months when they otherwise could have been eligible.

The very complex issues that surround the Part A enrollment and QMB eligibility and proposed solutions are discussed at length in three papers, written by different organizations, referenced in the note below.[11]

Field 2: Enrollment – Recertification requirement for Medicaid:

[11] Center for Medicare Advocacy, *Can You Be a "Qualified Medicare Beneficiary" If You Don't Have Medicare Part A?,"* June 2009 (available at: http://www.medicareadvocacy.org/Projects/AdvocatesAlliance/IssueBriefs/09_10.19.QMBsWithoutPartA.pdf); Center for Medicare Advocacy, *The QMB Benefit: How to Get It, How to Use It,*, June 2010 (available at: http://www.medicareadvocacy.org/Projects/AdvocatesAlliance/IssueBriefs/10_06.14.QMB.pdf); Medicare Rights Center, *Streamlining Medicare and QMB Enrollment for New Yorkers*: *Medicare Part A Buy-In Analysis and Policy Recommendations*), February 2011 (available at: http://www.medicarerights.org/pdf/Part-A-Buy-In-Analysis.pdf)

We agree that states' Medicaid recertification requirements can create gaps in Medicaid coverage for dual eligibles. We encourage CMS to promote streamlining of state recertification rules by encouraging the adoption of policies that have been used elsewhere in Medicaid to promote retention and produce administrative savings. In particular:

- Elimination of in-person interviews;
- Use of ex parte redeterminations, in which agencies use data already available from other sources (for example the Supplemental Nutrition Assistance Program) to confirm eligibility;
- Passive redetermination, in which beneficiaries remain eligible unless they report changes. This policy is especially well-suited to the dual eligible population, as incomes are less variable than they are for those of working age;
- Elimination of the Medicare Savings Program Asset test (see below).

Field 3: Enrollment – Medicare Savings Program Asset Test:

Nine states, including the District of Columbia, have elected, through the Section 1902(r)(2) option, to eliminate their asset test for Medicare Savings Programs (MSPs). Because MSP benefit provides automatic enrollment into the Part D low income subsidy (LIS), individuals in those nine states who would not otherwise "pass" the LIS asset test can get full help in paying for their prescription drugs.

All 50 states and the District of Columbia have eliminated their asset tests for programs for children. Individuals with incomes low enough to qualify for MSPs are likely to have few assets of value beyond their homes and a small amount of life insurance, which makes an asset test unnecessary.

To address these issues, CMS should:

- Continue to press states to choose the option to eliminate their asset test for MSPs, or adopt definitions of assets no more restrictive than those used for LIS.
- Support legislative efforts to eliminate the asset test for both MSPs and LIS to better align these programs with the Affordable Care Act's new eligibility rules for Medicaid and for subsidies in the health insurance Exchanges and to increase administrative efficiencies.

6.) Appeals

Overarching principles for designing a more cohesive appeals system for dual eligibles include the following:

a. **Offer clear notice of rights to appeal and of reasons for denial of care.** Notice should include very clear information about the beneficiary's liability in cases where aid is paid pending the determination and the beneficiary loses the appeal.
b. **Promote maximum Medicare coverage**, so that where coverage exists under both programs, and Medicaid will pay pending a Medicare determination (this arrangement

should be promoted in all circumstances), the beneficiary has clear guidance about how to seek a Medicare determination or appeal.

c. **Offer aid paid pending** a coverage determination, as is required by Medicaid regulations incorporating due process requirements from *Goldberg v. Kelly*, 397 U.S. 254 (1970)
d. **Promote timely decision-making.** Medicare allows for expedited appeals in certain circumstances. If expedited appeals were also available in Medicaid, beneficiaries receiving aid pending appeal would limit their liability. Medicaid requires all decisions to be made within 90 days. Medicare has few clear decision-making limits outside of expedited appeals.
e. **Offer access to an in-person hearing before independent decision maker.** Medicare offers better access to an independent decision maker; Medicaid offers greater access to in-person hearing.

Field 1: Timeframes for filing an appeal related to benefits:

As long as separate appeals systems exist for Medicare and Medicaid, it is critical that individuals get clear notice of what system to use and what their time frames are for filing a regular appeal, an expedited appeal, if any, and an appeal with aid paid pending the outcome (or, if they have missed the deadline for continued benefits pending appeal, how to get their benefits reinstated pending the outcome). For services covered under both programs, appeals under one program should proceed and not be dependent upon either the filing or adjudication of an appeal under the other program. This is especially important where Medicare appeals – to the Administrative Law Judge level and beyond – including meeting an "amount in controversy threshold," but also matters more generally in getting needed Medicaid services to individuals, as Medicaid's timeframes for both filing appeals and adjudication of appeals are shorter than Medicare's.

Field 2: Access to State level or external review:

Medicaid generally provides quicker access to external review. If an integrated appeals system is created, speedy access to external review should be an element of it. As long as the appeals processes remain separate, the fact of Medicaid's more streamlined process reinforces the principle that Medicaid appeals should be allowed to go forward before completion of a Medicare appeal, where both programs cover an item or service. The Medicare QIO process, an external review available to beneficiaries being discharged from hospitals, SNFs, home care or hospice requires very quick action on the part of the individual seeking review, action at a time when their attention may be focused elsewhere or about which they do not have a good understanding. To make that process more effective, it should be automatic and not require action on the part of the beneficiary. CMS might review and consider whether the QIC process, currently the first level of external review for most Part A and B appeals, is of any value to beneficiaries. It often becomes an extra layer of process necessary only to get to the ALJ level.

Field 3: Continuation of benefits pending appeal:

Aid paid pending a first level of review is a due process gold standard in health care and should be extended to Medicare, or at the very least, to all dual eligibles for Medicare services, as it

reflects the understanding that low income people cannot afford to pay for their own care pending a determination of whether it will be covered. Generally speaking in Medicare, beneficiaries cannot enter the appeals process without getting the services for which they seek coverage, thus incurring financial liability. In some circumstances, Medicare allows for the filing of a "demand bill" in situations where a provider has declared that there will be no Medicare coverage, but the beneficiary wishes to get a formal Medicare determination. This is not, technically, an appeal, but it does serve to continue services, without up front payment, until the initial coverage determination has been formally made. In demand bill situations as well as aid paid pending situations in Medicaid, quick turn around on the part of the decision maker is critical to minimize the financial liability of the individual in the event they are unsuccessful in securing coverage. The fact that they may be liable should be made clear in relevant notices. Medicare Part D provides for expedited review through the ALJ stage of appeal. Expedited review should be made available in specific circumstances under both programs.

Field 4: Document notifying beneficiary of appeal rights:

Notices are the critical first step in informing individuals of their appeal rights. Much advocacy has been undertaken over many years to improve notices and much remains to be done. We are less concerned with the difference in Medicare and Medicaid notices than with the assurance that notices are clear, understandable, and tell people what they need to know to file appeals, including clear and specific reasons for denial (e.g., National or Local Coverage Determinations in Medicare, specific references to coverage manuals in Medicaid) and how to ensure aid paid pending an appeal. Additionally, where Medicare and Medicaid coverage exists for a particular service and that service is being denied, reduced or ended, the individual should get appeal notices from both programs, so that they can seek maximum coverage. This idea builds on earlier comments that Medicaid coverage or appeals should not be dependent on Medicare determinations.

Field 5: Timeframes for resolution of an appeal related to benefits.

Expeditious resolution of appeals is critical where a) a service has been denied or b) the beneficiary is incurring or will incur financial liability for the service if coverage is ultimately denied. Medicaid generally has a more streamlined appeals process, with fewer levels of appeal. As noted before, because Medicaid's processes may be easier to access and more expeditious in getting to resolution, dual eligibles should be assured simultaneous access to both appeals processes in circumstances where both programs offer coverage.

7.) Issues not directly addressed in the RFI

Low enrollment rates in the Medicare Savings Programs

The number of those eligible for but not enrolled in Medicare Savings Programs remains distressingly high. By some estimates, more than half of those eligible for QMB are not enrolled, and an even higher share of SLMB and QI beneficiaries are not enrolled.[12] Some of the issues identified in the RFI could improve the enrollment rate – in particular, eliminating or at least

[12] National Academy of Social Insurance, *Improving the Medicare Savings Programs*, June 2006.

greatly simplifying the asset test for MSPs would make it much easier to enroll. Similarly, simplifying income rules to match those for the Part D low-income subsidy would simplify the process.

CMS should also consider an outreach and enrollment campaign similar to initiatives used for the Children's Health Insurance Program (CHIP). Many Medicare beneficiaries are not even aware that these programs exist. It should be possible, using Social Security data matched with Internal Revenue Service data, to work with states to identify and target beneficiaries who are eligible but not enrolled in MSPs to notify them of the program and help them enroll. MA plans should also be required to encourage their members to apply for these benefits. CMS should also verify that MA plans are coordinating beneficiaries' cost-sharing appropriately with all Medicare Savings Programs.

Taking greater advantage of the LIS to MSP application process created by the 2008 Medicare Improvements for Patients and Providers Act (MIPPA) (discussed below) could also increase enrollment.

Part D low-income subsidy enrollment and Medicare Savings Program alignment and eligibility

The 2008 MIPPA legislation created a promising new pathway for dual eligible eligibility, by treating all applications for the Part D low-income subsidy (LIS) as applications for Medicare Savings Programs (and Medicaid) unless a beneficiary indicates otherwise. LIS application data are now sent to states on a regular basis, and states are to treat these data as an application for MSPs. However, many states have been reluctant to take full advantage of this new source of data. Many have required re-submission of data because their definition of income and assets are different from that used by Social Security. This defeats the purpose of a provision that was intended to streamline the enrollment process and increase the number of beneficiaries being served. CMS should step up its efforts to encourage states to take full advantage of the new data. For example, states should be encouraged to accept all Social Security Administration data as verified. If states do not eliminate the asset test (as we encourage above), at a minimum states should use existing flexibility to eliminate certain categories of income and assets that are not used for LIS determinations such as cash value of life insurance or in-kind support and maintenance.

Issues arising under the 2014 Medicaid expansion

Looking forward, we want to highlight an additional point at which programmatic coordination may become problematic as the Patient Protection and Affordable Care Act (ACA) is implemented.

The ACA authorizes the establishment of application, eligibility, and enrollment processes to support health insurance exchanges and expanded Medicaid. Beginning in 2014, people who have Medicaid under the new eligibility rules established by the ACA and people who have coverage through an exchange plan will need to transition to Medicare in a new context. This transition should occur as seamlessly as possible to prevent penalties, high out-of-pocket costs, and gaps in coverage.

Beginning in 2014, all state Medicaid programs will be required to provide Medicaid to those with incomes up to 138 percent of the federal poverty level (FPL), eliminate any asset or resource test, and use a modified adjusted gross income (MAGI) calculation to determine eligibility (the MAGI population).[13] In addition, many of the bureaucratic hurdles such as providing proof of income and assets will be eliminated for the MAGI population because states will be able to certify asset and income information provided on Medicaid applications through matching data with IRS tax records. However, the more generous 138 percent FPL threshold, elimination of the asset test, the MAGI income calculation, and data exchange with the IRS required by the ACA do not apply to individuals who are dually eligible for Medicare and Medicaid (the non-MAGI population.)

This means that once individuals become eligible for Medicare, states will be required to do a separate analysis of Medicaid eligibility, even for those who still have incomes below 75 percent of FPL, which can lead to individuals who are eligible for Medicaid to fall off the rolls once they become Medicare eligible.[14] For example, states will need to apply an entirely different income calculation to determine eligibility. Furthermore, states that impose an asset test on the non-MAGI population will have to determine if the individual now meets the asset test, which may disqualify them for Medicaid. Moreover, because states will no longer be able to confirm income and asset information through a data exchange with the IRS, upon becoming Medicare eligible non-MAGI individuals will potentially need to submit documentation to attest to income and asset information provided on an application.

Currently, many states are focused primarily on establishing enrollment systems for people who will be eligible for coverage through an exchange plan or Medicaid under the ACA. They are moving away from paper based applications and manual data entry for eligibility determinations. CMS should encourage states to also incorporate the Medicare population into new systems to ensure that older adults and people with disabilities will benefit from system modernization and streamlined enrollment processes.

If states and the federal government do not plan to appropriately transition beneficiaries who no longer qualify for Medicaid under the new rules, many will experience gaps in coverage and will likely be unable to access services once they become eligible for Medicare. CMS should work with states to ensure that they have systems in place to identify beneficiaries who are aging into Medicare and who will need to be screened and enrolled in Medicaid, Medicare Savings Programs, or other low-income assistance programs.

Retroactive coverage for Medicaid

There is not an alignment issue related to retroactive coverage but we want to be clear that such coverage is important to beneficiaries and full access to retroactive coverage should be retained. We note that such coverage is not available for Qualified Medicare Beneficiary premium and

[13] Patient Protection and Affordable Care Act of 2010, § 2002.
[14] Certain 209(b) states can have income and assets tests that are below 75% of the FPL. However, these states are also required to have a Medicaid 'spend-down' program. In addition, some states have chosen to increase the income levels to more generous standards.

cost-sharing benefits and urge CMS to work with Congress to eliminate this egregious anomaly in Medicaid.

Appendix: Additional supporting documents

Connecticut Department of Social Services
Medical Assistance Program
Provider Bulletin

PB 2003-113 November, 2003

TO: **All Medicaid Providers**
SUBJECT: **The Definition of and the Determination of Medical Necessity for Durable Medical Equipment (DME)**

This bulletin supersedes PB 2002-65.

It has come to the Department's attention that there may be a need for clarification about the process that the Department uses to make benefit coverage determinations for Durable Medical Equipment (DME), particularly in light of the 1999 settlement agreement in DeSario v. Thomas. In this settlement, the Department agreed to provide individual consideration for items not listed on the Department's fee schedule and put forth this policy in §17b-262-672 through 17b-262-682 of the Regulations of Connecticut State Agencies, "Requirements for Payment of Durable Medical Equipment". This bulletin clarifies the process that the Department employs in making decisions on coverage pursuant to these regulations.

Requests for individual consideration must: 1) meet the definition of DME, and 2) be medically necessary and medically appropriate. For prior authorization requests for items already on the Department's fee schedule, only medical necessity/medical appropriateness is at issue

Definition

The first step in the process is to determine whether the item in question meets all of the criteria in the definition of DME as adopted in § 17b-262-673, of the Regulations of Connecticut State Agencies. These state that the item in question must:

1. Withstand repeated use;
2. Be primarily and customarily used to serve a medical purpose;
3. Be generally not useful to a person in the absence of illness or injury; and
4. Be non-disposable

The definition adopted by the Department is identical to that employed by the federal Centers for Medicare and Medicaid Services (CMS) in the administration of the Medicare program. The Department recognizes, however, that one of the purposes of the Medicaid program is to enable each state, in accordance with all applicable statutory and regulatory requirements, to furnish rehabilitation and other services to help eligible families and individuals attain or retain capability for independence or self-care.

CMS has further elaborated on this definition as it applies to specific items in the DMERC manual (Durable Medical Equipment Regional Carrier manual-Region A). This manual is updated on a regular basis and is universally recognized as a health care industry standard as an aid for the identification of the clinical uses of DME.

While the Utilization Review (UR) staff at DSS does consult the DMERC manual, it is not the only tool that they employ in considering whether a requested item does, in fact, meet the definition of DME. If the item does not appear on the Department's fee schedule and it also is not listed as a covered item in the DMERC manual, staff shall look to other sources of information concerning the requested item. For example, they may request additional documentation from the prescribing practitioner, or they may consult with physicians at the University of Connecticut Health Center under the terms of a Memorandum of Understanding. Under this agreement, the Department may access faculty in the full range of medical specialties to assist in the determination of medical benefits. The staff must then arrive at their own conclusion as to whether the requested item meets the criteria specified in the regulation in order to be considered DME. This would include consideration of any documentation provided to the Department about the particular item requested. Every item shall be individually assessed as to whether it meets the Department's definition of DME. Items are not denied solely because they are in a particular category.

Medically Necessary/Medically Appropriate

If an item has been determined to meet the definition for DME, the second question is whether that particular item is medically necessary and medically appropriate for a particular Medicaid recipient. In making these decisions, the Utilization Review staff at DSS must evaluate the request for a particular item in light of the Department's definitions of medical necessity and medically appropriate. Both assessments must be based on an individualized assessment of the recipient and his or her medical condition, including documentation from the recipient's doctor and other providers and may include communication with the recipient.

In Section 17b-262-673 of the regulations of Connecticut State Agencies, the Department defines "medical necessity" as:

> "Health care provided to correct or diminish the adverse effects of a medical condition or mental illness; to assist an individual in attaining or maintaining an optimal level of health, to diagnose a condition or prevent a medical condition from occurring."

In the same section, the Department defines "medically appropriate" as:

> "Health care that is provided in a timely manner and meets professionally recognized standards of acceptable medical care; is delivered in the appropriate medical setting; and is the least costly of multiple, equally-effective alternative treatments or diagnostic modalities."

The definitions of "medical necessity" and "medically appropriate" must be applied to each individual once it has been determined that the item requested meets the definition of DME. An item could qualify as DME but it may or may not be medically necessary for a given individual. It may be medically necessary for that individual, but it may or may not be medically appropriate depending on whether the UR staff determine, among other things, that the item is "the least costly of multiple, equally-effective alternative treatments or diagnostic modalities."

While the DMERC Manual provides broad guidance for which items meet the definition of DME and when such items can be determined to be medically necessary and/or medically appropriate for an individual client, it is never the sole basis for denial of a request for coverage. It is a reference point, but it is just that. Additional documentation is received, as described above, and the ultimate determination is based on the criteria specified in the Department's regulations, §17b-262-672 through 17b-262-682.

I hope that this bulletin has provided some clarification about the range of activities that we are engaged in to assure that every request for DME receives a comprehensive review for our clients. If you have any questions, please email your questions to Mark Schaefer at mark.schaefer@po.state.ct.us or Evelyn Sebastian at evelyn.sebastian@po.state.ct.us.

David Parrella, Director
Medical Care Administration

This bulletin and other program information can be found at **www.ctmedicalprogram.com.**
Questions regarding this bulletin may be directed to the EDS Provider Assistance Center - Monday through Friday from 8:30 a.m. to 5:00 p.m. at:
In-state toll free.....**800-842-8440** or
Out-of-state or in the
local New Britain, CT area **860-832-9259**

EDS
PO Box 2991
Hartford, CT 06104

NEW HAVEN LEGAL ASSISTANCE ASSOCIATION, INC.
426 STATE STREET
NEW HAVEN, CONNECTICUT 06510-2018
TELEPHONE: (203) 946-4811
FAX (203) 498-9271

November 22, 2010

Donald Berwick, M.D.
Administrator
Center for Medicare and Medicaid Services
Dept. of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Re: Pharmacy Access Issue Broadly Impacting Medicare and Medicaid Enrollees' Access to Quality Care; Uniform National Solution Needed in Place of Limited Medicare Rule

Dear Dr. Berwick:

We are a coalition of consumer advocates with extensive experience helping beneficiaries who confront pharmacy access problems in both the Medicare and Medicaid programs. We write to alert you to a time-sensitive opportunity to significantly improve the quality of patient care for Medicare and Medicaid beneficiaries. This can be accomplished by requiring that patients receive the timely written information they need when prescribed drugs cannot be dispensed at the pharmacy, owing to the payers' use of formularies and preferred drug lists (PDLs), or similar restrictive administrative policies.

Fortunately, policies are now being developed on the Medicare side of your agency which can, with some modification, improve quality nationwide for **both** Medicare and Medicaid programs, thereby improving access to care for millions of low-income vulnerable recipients. Information technology systems that have been in place for over a decade throughout the country can readily accommodate patients' needs for timely information. But this will require your leadership to ensure those needs are addressed. On November 10, 2010, CMS announced that it is issuing proposed Medicare Part D rules. See http://www.cms.gov/apps/docs/Fact-Sheet-2011-Landscape-for-MAe-and-Part-D-FINAL111010.pdf. (CMS Proposed Regulation CMS-4144, currently available at www.regulations.gov.) Unfortunately, **the proposed rules fail to fully take these needs into account, and do not effectively address quality concerns.** Given Medicare's role as industry leader, it is imperative that these rules "get it right," since they will likely set the industry-wide standard for years to come, affecting quality for *all* patients, not just Medicare and Medicaid beneficiaries. In addition, as a matter of basic fairness and efficiency, the new requirements should be made to apply simultaneously to both Medicare and Medicaid.

The basic problem derives from the fact that prescribers, unable to keep track of which drugs require prior authorization (PA) or an "exception" (in the case of Medicare Part D) under which plans at any given time, regularly write prescriptions for PA-only drugs without first requesting PA, resulting in electronic denials at the pharmacy. And when this occurs, under current Medicare and Medicaid systems, no written information about the steps needed to correct these denials (request PA, prescribe a formulary alternative, appeal an erroneous determination)

is provided directly to the individual. Thus, individuals are routinely denied payment for their prescribed drugs – or any alternative drug -- at the pharmacy, and do not know where to turn. As problematic as these kinds of denials are for anyone, they are particularly troubling for low-income individuals, many of whom are disabled or elderly, with chronic medical conditions. This population is likely to have poor access to transportation, limited education and few alternative resources such as credit cards. The millions with limited English language proficiency face additional barriers as they try to cope with the denial of prescriptions their doctors have written.

The only effective solution is to require that all Medicare and Medicaid payers arrange with their pharmacy contractors for the issuance of **electronically-generated, individually-tailored written notices to be immediately provided to the enrollee at the point of sale**, whenever they deny a drug electronically for any reason. The proposed Medicare rule does make a major step in the right direction in this regard, but it does not go far enough, particularly in failing to require an individually-tailored notice to be issued in all cases. We will be separately commenting on the notice of proposed rule-making, but the problem is broader than Medicare. We need your leadership to ensure that a comprehensive uniform notification procedure containing all of these critical elements, fully applicable to both programs, is timely promulgated.

Included with this letter is a background document explaining how pharmacy computer systems work, the negative impact on patient compliance of payers' routine electronic denials at the pharmacy (including data from two states), the illegality of failing to provide individually-tailored notice under federal Medicaid and Medicare rules, the specifics of our proposed solution, and our serious concerns with the proposed rule-making on the Medicare side.

While this should explain the problem and the solution in sufficient detail, we also request a meeting with you as soon as possible at which we can discuss the implementation of our proposed solution.

Thank you for your immediate attention to this important matter affecting every Medicare and Medicaid enrollee in the country. We are very grateful for your leadership and are excited by all that you and your staff are doing to improve health care for all Americans.

Respectfully yours,

Sheldon V. Toubman
Staff Attorney

And on behalf of:

Leonardo Cuello
National Health Law Program

Gordon Bonnyman
Tennessee Justice Center

Ilene Stein

Georgia Burke

Medicare Rights Center

Vicki Gottlich
Center for Medicare Advocacy

National Senior Citizens Law Center

Diane F. Paulson
Medicare Advocacy Project
Greater Boston Legal Services
on behalf of its clients

Enc.
cc: Cynthia Mann, Deputy Administrator and Director, Center for Medicaid, CHIP, Survey & Certification
Jonathan Blum, Deputy Administrator and Director, Center for Medicare