



Summary and Preliminary Analysis of Chronic Care Provisions of House and Senate Medicare Prescription Drug Bills as Approved in Committee.

The legislation approved in each of the three Committees has multiple provisions addressing chronic care issues. The NCCC has been involved in development of several of the provisions and we believe that, taken together, the provisions are an important recognition of the need to re-orient the health care system toward better chronic care and are an important start to that process.

The Senate Finance Committee approved its Prescription Drug and Medicare Improvement Act on Thursday, June 12th. The House Ways and Means Committee, which has jurisdiction over Medicare Parts A, B, and C approved, along party lines, H.R. 2374, The Medicare Prescription Drug and Modernization Act of 2003 on Tuesday, June 17th. The House Energy and Commerce Committee, which has jurisdiction over Medicare Parts B and C, approved H.R. 2374 on Friday, June 20th.

This document summarizes the two bills as they were approved by the Committees and prior to floor action in each chamber. (Changes can occur on the floor via amendment in either chamber.) After the legislation is approved on the floor of each chamber, there will be negotiations between the House and Senate to resolve differences among the bills, with one bill emerging from this “conference” negotiation for another vote on it in each chamber. As of June 25th, there are negotiations in the Senate to expand the role demonstrations related to disease management and chronic conditions in the traditional program. As we find out more details, we will let you all know.

The Senate Provisions:

Sec. 101, Prescription Drug Coverage and Chronic Conditions: The Senate bill provides that all prescription drug contractors must have in place a utilization management program to encourage the use of generics and therapeutic interchange. Each contractor must also have a quality assurance program to reduce errors and adverse interactions. The QA program would include a medication therapy management program targeted to beneficiaries with chronic conditions or who take multiple prescriptions. The program would be designed to reduce the risk of adverse drug events and to optimize therapeutic outcomes. The program may include: beneficiary education; features to improve treatment compliance; detect patterns of underuse or overuse. There are also requirements for contractors to develop programs for electronic prescribing

Sec 443. Medicare Complex Clinical Care Management Payment Demonstration. This provision would create a 6 site (3 urban, 3 urban, 1 in Arkansas), three year demonstration program which would begin in October 2004. Under the demonstration, there would be monthly administrative payments made to physicians who agree to be principal care physicians for participating, eligible beneficiaries. Eligible beneficiaries are those who have at least four complex medical conditions (including cognitive impairment) and have an inability to self-manage care, or have at least four complex medical conditions and one ADL or IADL limitation.

Eligible physicians can be either primary care specialist or other specialist who enters into an agreement with the Secretary to manage clinical care by: serving as the principal contact for the participating beneficiary; maintaining a medical record that includes information from other treating providers (treatment regimens, diagnostic tests and results, etc); advocating for continuity of care for participating beneficiaries; using evidence-based guidelines, promoting self care and family caregiver involvement; having appropriate staffing arrangements to conduct patient self-management and other care coordination activities; referring beneficiaries to community-based services and coordinating those services with medical

treatment; and comply with other standards established by the Secretary. These principal care physicians would coordinate care according to a written plan of care.

The demonstration would operate with a budget neutrality provision wherein the Secretary must ensure that aggregate spending under the demonstration does not exceed what would have otherwise been spent in the absence of the demonstration.

Discussion: This provision is, in part, based on the NCCC complex clinical care management fee proposal, with some critical differences as the Senate staff sought a substitute for a larger case management benefit as proposed by Senator Lincoln (D-AR).

In terms of beneficiary eligibility, CMS will have to sort out a definition of ‘complex’ medical conditions. Arguably, four complex conditions is a high standard. Most of the predictive risk methodology in use today (the algorithms from which could be used to determine eligibility under this demonstration) employ a concept of ‘major’ condition, sub-stratified into major acute and major chronic conditions. Thus there is an established literature, methodology and precedent to consider adapting the concept of ‘complex’ to ‘major’ by linking concepts of high utilization and high costs. However, simply adopting ‘major’ as a proxy for complex may yield a very, very high cost, complex eligibility pool, suitable for nursing home placement – a service not covered under Medicare and thus complicating the budget neutrality calculations. The demonstration might be more workable if beneficiaries with four or more conditions, one of which is major, were made the eligible pool.

Another, concurrent beneficiary eligibility criteria is an inability to self-manage care. In operationalizing this, CMS could provide that beneficiaries with a diagnosis of Alzheimer’s or other ‘code-able’ cognitive impairments would be deemed to have difficulty self-managing care. NCCC would also suggest that CMS could, in addition to deeming cognitive impairments, further operationalize this criteria using other ‘code-able’ events that would be proxies for inability to self-manage care: seeing multiple Medicare providers in a set prior period of time (such as three or more provider visits in the previous three months) and concurrent use of a threshold number of unique prescriptions. These would minimize program integrity issues while remaining true to the intent of the provision. Operationalizing the ADL/IADL criteria will likely require the use of a screening/assessment tool, with which geriatric specialists will be immediately familiar. For other physicians, it may be more appropriate to use the threshold proxies.

There are indications of other potential operational issues that would merit further discussion as CMS moves to implement the demonstration. The NCCC members and other providers who treat people with multiple and complex conditions generally believe that it is not always appropriate to adhere strictly to various and multiple disease treatment guidelines because of the complicated nature of multiple conditions and the related interactions which are not always accounted for in specific guidelines. NCCC would suggest that, if this standard is to remain in statute, then CMS should be flexible as to application and consult with practitioners familiar with this target population in establishing the standard.

The language of the statute would seem to allow a principal care physician to contract out patient self-management education and caregiver education – which seems like appropriate flexibility to help ensure this necessary and important function is conducted by those best able to do it.

Finally, there is the issue of budget neutrality. If the computation is done on a demonstration-wide basis, the budget neutrality would not be a barrier to implementation. However, if it is calculated on an individual provider level, there will, of course, be issues of viability.

Sec 444. Medicare FFS Care Coordination Demonstration Program: This is a five year, six site, budget neutral, demonstration wherein the Secretary is to give preference to establishing the demonstration in



rural sites. Under the demonstration, eligible beneficiaries (defined as high risk: nursing home residents; those with Multiple Sclerosis or another disabling chronic condition; those at risk of nursing home placement; or dual eligibles) elect to participate and select a care management organization (CMO).

A CMO can be: a physician group practice, hospital, home health agency, hospice, disease management company, an M+C or Medicare Advantage plan, Medigap insurer, and other entities as the Secretary may specify. CMOs receive payment for care management activities and contract under partial risk for those payments. (CMOs are not at risk for Medicare covered services under this particular provision.) CMOs must operate within quality and cost benchmarks established by the Secretary. Those not meeting the benchmarks would lose a portion of their fees. The contractor risk arrangement operates within an overall budget neutrality provision requiring the Secretary to ensure that aggregate costs under the demonstration would not exceed costs that would have been incurred in the absence of the demonstration. Care management services must be consistent with standards established by the American Geriatrics Society.

Discussion: A potentially problematic feature of the demonstration is the description of eligible beneficiaries: those at high risk including those with possibly one chronic condition. In general, the NCCC believes that care coordination services (particularly coordination of clinical care) are most necessary for people with multiple complex conditions. Beneficiaries with a single condition—albeit a serious and disabling condition—may not have a need for clinical care coordination/management services such that costs might be greater under a system of care management than might otherwise be incurred in the absence of a system. This is not to say that care coordination is not useful for all people with a serious chronic condition, but that in the context of budget neutrality, this could be problematic. Therefore, how the potential contractors define the eligible population could have significant bearing on the budget neutrality. It is also not clear whether a CMO could select (or otherwise narrow) the eligible population it would chose to serve or if they would have to be open to all statutorily defined eligibles in the service area.

The budget neutrality provision should not pose exceptional barriers to implementation if costs are calculated for the demonstration as a whole. If the calculation is made on a contractor by contractor basis, then the demonstration may no longer be evaluating simply concepts of care management delivery, but rather ability to sustain full financial service risk in the delivery of care coordination services.

Like the other Senate demonstration, this demonstration will test the important concept of how care management services should be structured to affect service utilization (and provider behavior, a key source of utilization) to achieve better client outcomes and more appropriate utilization. NCCC believes that in order to change systems to improve chronic care for people with complex and multiple conditions, greater active physician involvement is required, with properly aligned incentives coupled with responsibility and accountability. While patient education and self-management clearly have a significant role to play, when clinical needs are complex and beneficiaries are seeing multiple physicians who are each prescribing treatment regimens, physician involvement will be required. So this demonstration could test whether entities without a specific relationship with individual physicians can accomplish this goal.

Sec 222, Specialized M+C Plans for Special Needs Beneficiaries: This provision would create a category of Specialized M+C plans that can exclusively enroll and serve beneficiaries with special needs. Special needs beneficiaries are defined as those who reside in nursing homes, dual eligibles, or other special needs groups as the Secretary may identify. This special plan status expires in 2008.

Discussion: This provision was added to permit the United Health Care Evercare demonstration program to move into the M+C program with the exception that it would not have to meet the M+C marketing and



enrollment rules that require marketing to all interested beneficiaries in the service area. Evercare could continue to operate a program outside of demonstration authority and enroll select groups of beneficiaries for its specialized program. It would also allow other plans to exclusively enroll special needs beneficiaries. The provision does not appear to account for the fact that the M+C program is changed to the Medicare Advantage program that becomes operational in 2006. All Medicare Advantage plans must offer prescription drug coverage and catastrophic coverage.

House Chronic Care Provisions:

Sec. 101, Prescription Drug Coverage and Chronic Conditions: The House bill is similar to the Senate language and provides that all prescription drug contractors must have in place a utilization management program to encourage the use of generics and therapeutic interchange. Each contractor must also have a quality assurance program to reduce errors and adverse interactions. The QA program would include a medication therapy management program targeted to beneficiaries with chronic conditions or who take multiple prescriptions. The program would be designed to reduce the risk of adverse drug events and to optimize therapeutic outcomes. The program may include: beneficiary education; features to improve treatment compliance; detect patterns of underuse or overuse. There are also requirements for contractors to develop programs for electronic prescribing.

Sec. 611, Physical Exams: The House bill would provide coverage of a one-time, initial physical exam for all beneficiaries becoming eligible for the program on or after January 1, 2004. Coverage excludes clinical lab tests. Beneficiaries would not have to pay deductibles or coinsurance on this benefit and must avail themselves of the service during the first six months of their enrollment in Medicare. The content of the exam would be determined by the Secretary. Coverage is available for all beneficiaries becoming eligible for Medicare on or after January 1, 2004.

Sec. 612, Cholesterol Screening: Beginning on January 1, 2005, Medicare would cover cholesterol and other lipid screening services not more frequently than every two years. Deductible and co-payment obligations apply.

Sec. 613, Colorectal Cancer Screening: Beginning January 1, 200, there would be no beneficiary co-insurance for covered colorectal cancer screening services.

Sec. 233, Specialized Medicare Advantage Plans for Special Needs Beneficiaries: This provision would create a category of Specialized Medicare Advantage plans that exclusively or disproportionately enroll and serve beneficiaries with special needs. Special needs beneficiaries are defined as those who reside in nursing homes, dual eligibles, or other special needs groups as the Secretary may identify. This special plan status expires in 2007.

Discussion: The basic provision was added to permit the United Health Care Evercare demonstration program to move into the M+C/Medicare Advantage program with the exception that it would not have to meet the marketing and enrollment rules that require marketing to all interested beneficiaries in the service area. Evercare can continue to operate a program outside of demonstration authority and enroll select groups of special needs beneficiaries for its specialized program. It would also allow other plans to exclusively enroll special needs beneficiaries. The provision does not account for the fact that the Medicare Advantage program becomes operational in 2006 and all Medicare Advantage plans must offer prescription drug coverage and catastrophic coverage.

The provision was amended during House Energy and Commerce mark-up to include in the definition of specialized plans, those that disproportionately enroll special needs beneficiaries. The amendment was



requested by the Medicare Payment Coalition and the NCCC to gain a starting point for recognizing unique needs of serving a complex patient population in a health plan setting.

Sec. 721, Voluntary Chronic Care Improvement Under Traditional Fee For Service: The House bill allows vendors/contractors to bid to offer a Chronic Care Improvement Program (CCIP) in regions of the country. The size of the regions would be determined by the Secretary. At least two programs would be offered in each region. Contractors can be a disease ‘improvement’ organization, health insurers, provider organization, a group of physicians, or any other legal entity determined appropriate by the Secretary. Winning contractors will identify potential enrollees who it wishes to serve, who will then be contacted by the Secretary to inform them of the CCIP and its benefits. While contractors are allowed to identify potential beneficiaries to serve, the general language of the section indicates that CCIPs are intended to serve traditional program enrollees who have “certain” chronic conditions and continues on to list several including CHF, diabetes, COPD, stroke or others.

Winning contractors must develop for each enrolled beneficiary a CCI Plan that would focus on: self improvement education; education for providers and primary caregivers and family members; coordination of health services, collaboration with physicians; use of monitoring technologies; information on hospice, pain management and palliative care as appropriate. Contractors would: “guide participants in managing their health...” including comorbidities; use decision support tools such as evidenced-based guidelines; develop clinical information databases to track and monitor participants. CCIP contractors could use subcontractors. The Secretary is to assure that there will be no net increase in aggregate Medicare payments in a three-year period beyond what would otherwise have occurred (including administrative costs). Contracts must include risk-sharing and payments subject to meeting clinical and financial performance standards established by the Secretary. Clinical trials would be established to assess costs and outcomes.

Discussion: The program appears to be oriented toward standard disease management operations, which was reinforced during the mark-up by Ways and Means Health Subcommittee Chairwoman Johnson. It is not clear that this provision will address the needs of medically complex elders, and those who have multiple chronic conditions, since the general language has a focus on single disease states. There is a service focus on self-management, which is the hallmark of current disease management vendors. While the language recognizes and requires vendors to address comorbidities, NCCC believes it may be beyond the scope of most traditional disease management vendors to guide beneficiaries in self-management when 20 percent of the Medicare population has 5 or more chronic conditions (almost all of whom have at least one major condition) and see an average of 14 unique providers in a year and fill almost 50 prescriptions.

Because the program emphasis appears to be on more traditional disease management strategies, there is no apparent emphasis on coordination of clinical care and there is no emphasis on a role for clinical providers beyond requiring vendors to collaborate with physicians, which occurs today to greatly varying degrees, typified by receiving information from vendors. Given the lack of focus on the population most in need of chronic care coordination where the bulk of program costs lie, it is not clear what type of savings can be generated with traditional strategies.

If there is a focus on those with the most serious and complex cases, it is not clear where a vendor will derive the authority to affect physician-directed utilization nor resolve conflicting treatment regimens prescribed by the many treating providers. It is also not clear whether how beneficiary education will surmount the challenges of cognitive impairments present in at least ten percent of the Medicare population and which are highly correlated with dramatically increased costs for each common chronic condi-



tion in the Medicare population. NCCC believes that the research done by NASI, Chen and others have shown that demonstrated care management cost savings are difficult to find when care management is not in some way tied substantially to treating providers. A substantial tie can occur within integrated settings. It is not clear from the language how competing plans will bid, and how those bids would be evaluated, particularly if the target enrollee population is different among the bidding organizations. Finally, the correlation or operational link between risk sharing, budget neutrality, and the clinical trials is as yet unclear. The Secretary will likely have to operationalize budget neutrality long before clinical trial results on costs and outcomes will be complete.

NCCC would recommend that winning contractors demonstrate a process of investing treating providers in the CCIP and demonstrate how it will coordinate among multiple treating providers of the same beneficiary.

Sec. 722, Chronic Care Improvement Under Medicare Advantage (MA) or Enhanced Fee for Service (EFFS) Plans: Each health plan contractor under either Medicare Advantage or EFFS would be required to have chronic care Improvement Program (CCIP) for beneficiaries with multiple or “sufficiently” severe chronic conditions. With the exception of the target population, the program description is the same as in section 721 in the traditional program.

Discussion: While the target population is different than the target population for the traditional program CCIP, the requirements are the same. It would appear that most current disease management organizations and current health plan in-house or vendor programs would meet the criteria. (Virtually all US health plans have a diabetes disease management program, and about 40 percent have seven or more disease management programs.) It is not clear how current disease management programs can meet the needs of beneficiaries with multiple serious chronic conditions, including cognitive impairments. NCCC believes that health plans should be required to demonstrate a process by which clinical care is coordinated for people with multiple (and varying) chronic conditions without regard to the specific diseases, such as sentinel medical information in electronic form available to treating plan providers. Plans should ultimately have to provide outcomes information and meet benchmarks over time such as reduced incidence of ambulatory care sensitive hospitalizations and/or the extent to which physicians access the information made available to them.

Sec. 723, Institute of Medicine (IOM) Report: This provision would require the IOM to conduct a study of the federal and state statutory and regulatory barriers to effective integrated care for Medicare beneficiaries with multiple or severe chronic conditions across settings and over time. The report would be due within 18 months of enactment. Specifically, the IOM is to examine impediments to coordinating care for beneficiaries in transition, particularly between institutional settings, and institutional settings and home health or home. Study aspects include clinical, financial and administrative requirements that stymie effective, seamless, transitions; policies that impede creation of administrative and clinical tracking systems across setting. The IOM would consult with experts in the field of chronic care, consumers, and family caregivers in developing its report.

Discussion: The NCCC requested this report and views it as a crucial step in moving the health care system forward to improved chronic care delivery. With the important examination of the transitions issues by the expert IOM, policymakers will be better able to identify discrete areas in which to begin to take concrete steps to effect change and improvement at the state and federal levels, in an area where multiple interactive policies currently stymie efforts at change.

