Report to Congress—Review and Report on Current Standards of Practice for Pharmacy Services Provided to Patients in Nursing Facilities

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Executive Summary

Section 107(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requires that the Secretary of Health and Human Services conduct a study of current standards of practice for pharmacy services provided to Medicare beneficiaries residing in long-term care (LTC) facilities, and submit a report to Congress on the study conducted. The study must review current standards of practice for pharmacy services provided in LTC facilities, and evaluate the impact of those standards with regard to patient safety, reduction of medication errors, and quality of care. The report must include (a) a description of the plans of the Secretary to implement Title I—Medicare Prescription Drug Benefit, aka Part D, in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of LTC facility patients, and (b) recommendations of the Secretary regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to Medicare beneficiaries residing in LTC facilities, in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

The Centers for Medicare & Medicaid Services (CMS) conducted the study reviewing long-term care pharmacy (LTCP) standards of practice. Current standards have evolved over several decades, in response to a complex set of Federal and State regulations governing the provision of prescription drugs in the LTC setting. To ensure compliance with those regulations, the LTCP market has settled on a set of customary specialized services most nursing facilities (NFs), including skilled nursing facilities (SNFs), expect from their pharmacy provider, to ensure that their residents receive timely access to safe and appropriate therapies. For safety and efficiency reasons, many NFs contract with a single preferred and dedicated LTCP to provide these specialized services.

Industry-wide, Medicaid is the biggest payer for pharmacy services. And, Medicaid pharmacy rates represent a pricing floor that establishes a guaranteed minimum reimbursement rate to LTCPs. LTCPs compete for NFs by offering many specialized services, including consultant pharmacist services for drug regimen reviews, for little or no explicit additional charge. The vast majority of NF beds are served by LTCPs. Most of those beds are served by four national chains, with the remainder served by independent pharmacies. National chain LTCPs maintain their own geriatric-specific formularies and many Medicaid programs have preferred drug lists.

In accordance with the study, the Secretary and CMS have taken numerous steps to ensure that the Part D drug benefit functions well in LTC settings. On January 28, 2005, CMS published the Final Rule implementing Title I and creating Part D plans. In addition, CMS has released several pertinent guidance materials, including Part D plan application submission materials, LTC stakeholder guidance, a list of LTC facilities, a list of pharmacies interested in participating in LTCP networks, guidance regarding coverage of over-the-counter (OTC) drugs, guidance regarding the transition process, a transition plan for Medicare-Medicaid dual-eligibles, guidance to State Medicaid Directors regarding coverage of benzodiazepines, emergency coverage

guidance, and Part D plan payment rate methodology. Taken together, the Final Rule and pertinent guidance materials constitute the plans of the Secretary.

The general structure of the plans of the Secretary is as follows. Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC network, as long as the pharmacy is prepared to comply with relevant State laws and to meet certain performance and service criteria. Plans will also be required to demonstrate that they have a network of participating pharmacies that provides convenient access to Part D enrollees who are LTC facility residents. These requirements will permit LTC facilities to continue to contract exclusively with one LTCP or with as few as possible, and also provide facilities with an incentive to select pharmacies that contract with a large number of Part D plans and that offer specialized LTCP services at competitive prices. To ensure access to medically necessary drugs for LTC facility residents, a Part D plan may include those key drugs in its formulary or provide appropriate exceptions processes. Also, by statute, institutionalized full-benefit dual-eligibles, who constitute approximately half of Medicare beneficiaries residing in LTC facilities, will be totally exempt from any cost sharing. To facilitate the period of transition to Part D, dual-eligibles will be auto-enrolled in the fall of 2005, and plans will be required to establish an appropriate transition process. For dual-eligibles, benzodiazepines and OTCs must continue to be covered by Medicaid, unless a State specifically chooses to eliminate such coverage for all its Medicaid recipients. Also, plans may cover select OTCs that are part of step therapy protocols, at no cost to the beneficiary. Finally, Part D payment rates will be risk adjusted for the increased drug spending of institutionalized enrollees. Specifically, for aged institutionalized enrollees, the adjustment factor is 1.08, and for disabled institutionalized enrollees, the adjustment factor is 1.21.

The plans of the Secretary address the reimbursement and patient safety issues raised by the study conducted by CMS of current financing and delivery standards of practice. Consequently, the Secretary has no legislative recommendations at this time. However, given that Part D is a new program, it will be essential to monitor broadly early experiences with implementation. If necessary, the Secretary will make recommendations for actions, based upon the implementation and early operational experiences of the Part D program.

Summary of Study Conducted

Section 107(b) of MMA specifies that the study conducted review current standards of practice for pharmacy services provided in LTC facilities, and evaluate the impact of those standards with regard to patient safety, reduction of medication errors, and quality of care. CMS contracted with the Lewin Group, Inc., to conduct the study, the Final Report for which is attached. In accordance with the legislative mandate, the study focused on NFs, including SNFs, which meet specific regulatory certification requirements.

In conjunction with the study, a Special Open Door Forum (ODF) was held by CMS on November 16, 2004, entitled Listening Session on Current Standards of Practice for Pharmacy Services provided to Medicare Beneficiaries Residing in Long-Term Care Facilities. The Special ODF was held to allow CMS to hear from LTCP stakeholders regarding issues involved

in the implementation of Part D, and to allow those stakeholders an opportunity to provide input regarding this study.

For the study, an information scan of existing data sources was conducted to gain an extensive and critical understanding of current standards of LTCP practice, both financing standards and delivery standards, for pharmacy services provided to Medicare beneficiaries residing in LTC facilities, how those standards evolved, and how they vary across states. Following is a summary of findings from the study.

Current standards of practice in LTCP have evolved over several decades, in response to a complex set of Federal and State regulations governing the provision of prescription drugs in the LTC setting and designed to ensure patient safety. At the Federal level, conditions of participation for NFs accepting Medicare and Medicaid funding are derived from the Omnibus Budget Reconciliation Act of 1987 and the Omnibus Budget Reconciliation Act of 1990. Each State's Survey and Certification Agency is responsible for certifying that NFs in the State accepting Medicaid funding meet the Federal conditions of participation. Specifically, certified NFs must have low medication error rates, reduce unnecessary drug use, and conduct monthly drug regimen reviews for residents. In addition, certified NFs cannot impose upon residents chemical restraints that are not medically indicated (42 Code of Federal Regulations (CFR) §423.13). Each State's Department of Health and Board of Pharmacy is also responsible for licensing of NFs and pharmacies, and for licensing of NF and pharmacy professionals. Licensing requirements vary widely across states. Finally, at the Federal level, the Food and Drug Administration approves drugs and sets manufacturing and labeling standards, while the Drug Enforcement Administration assures that drugs are not diverted for non-medical uses.

To ensure compliance with Federal and State regulations, the LTCP market has settled on a set of customary specialized services that most NFs expect from their pharmacy provider. These specialized services, which ensure that NF residents receive timely access to appropriate medication therapies, are generally beyond the scope of services provided by retail pharmacies to beneficiaries who reside in the community. Therefore, for both safety and efficiency reasons, many NFs contract with a single preferred and dedicated LTCP to provide the following prescription drug and consultant pharmacist services.

- Prescription processing—create medication record, clarify medication order when necessary, respond to emergency medication orders, perform drug utilization review, and apply formulary or preferred drug list.
- Dispensing and delivery—package medication in unit doses, ensure proper labeling, provide timely delivery, maintain emergency kits, maintain interim kits, and maintain floor stock.
- Medication administration—perform quality assurance checks and supply medication carts.
- Consultant pharmacist services—perform drug regimen reviews per Federal mandate, review and document processes of care, monitor drug storage and inventory, provide formulary recommendations to the LTCP, and educate NF staff regarding cost-effective therapies.
- Handling of unused medications—accept return of unused medications and assist in appropriate disposal of controlled and non-controlled substances.

Industry-wide, Medicaid is the biggest LTCP payer, accounting for 60-65 percent of pharmacy revenue, with Medicare Part A, commercial payers, and private payers each accounting for

approximately equal shares of the remainder. Pharmacy reimbursement to LTCPs, services covered, and the degree to which LTCPs have the flexibility to negotiate payment vary across payers. LTCPs are usually reimbursed on a fee-for-service (FFS) basis for the drugs they dispense to residents in NFs. Those reimbursement rates generally cover ingredient costs and basic dispensing fees only, with no additional payment for the other specialized services LTCPs typically provide.

Those specialized services are likely partially subsidized by manufacturer rebates to the LTCP, especially to national chain pharmacies, and by the spread between the acquisition cost for and the reimbursement to the LTCP. Also, Medicaid pharmacy rates reimburse LTCPs for ingredient costs and basic dispensing fees at legislatively determined rates on a FFS basis that varies across States, and those rates are likely partially subsidizing many specialized services that are not explicitly covered by the pharmacy reimbursement. Although those specialized services are allowable under the Medicaid NF rates, as opposed to the pharmacy rates, it is currently customary for LTCPs to compete for NF business by offering these specialized services at little or no charge.

When LTCPs do charge for services, it is often at rates that are below the cost of providing the service. The following estimates assume a typical 100-bed facility and 10 prescriptions per month per resident. LTCPs usually charge NFs a fee for consultant pharmacy services (fee of approximately $0.40-$1.00 per prescription, to cover costs of approximately $0.50-$1.50 per prescription), and occasionally charge for maintaining medical records (fee of approximately $0.20-$0.50 per prescription, to cover costs of approximately $0.40-$0.50 per prescription), but provide a number of additional specialized services to the NFs for no additional charge (to cover additional costs of approximately $2.25-$6.00 per prescription).

SNFs receive a prospective payment reimbursement for Medicare Part A residents. The rates that SNFs pay LTCPs for pharmacy services provided to those residents is usually the same as Medicaid FFS rates, in part because Medicaid pharmacy rates act as a pricing floor in the industry. This means that Medicaid rates represent a guaranteed minimum reimbursement to LTCPs. Commercial payers, including many managed care payers, and private pay residents also reimburse LTCPs on a FFS basis. Commercial payers typically pay the lowest rates in the market, due to some negotiation below the floor, and private pay residents typically pay the highest rates.

The LTCP market represents approximately $8 billion in annual revenues. The nature of the specialized services provided by LTCPs and the fact that LTCPs need high penetration of beds per NF to support delivery costs strongly favor a one-to-one model of a single LTCP serving each NF. In addition, because the one-to-one model may facilitate patient safety, it dominates the market. Exceptions to that model exist in rural areas and in a few States, where some NFs are served by local retail pharmacies that do not specialize in LTCP and by Veterans Association (VA) mail order pharmacies. However, the vast majority of NF beds are served by LTCPs. Four national chain LTCPs serve approximately 55-60 percent of the beds served by LTCPs, with approximately 40-45 percent served by independent LTCPs. Independent and national chain LTCPs generally provide the same types of services. National chains have lower costs due to scale, but independents have lower overhead costs because typically they are located closer to

the facilities they serve. NFs tend to select LTCPs primarily based on quality of service and price, and tend not to change LTCPs often, because the start-up monetary and time costs associated with changing to a new LTCP are relatively high.

National chain LTCPs maintain their own geriatric-specific formularies, which are developed by their own Pharmacy and Therapeutics committees with geriatric expertise, and for which they are positioned to achieve high levels of formulary compliance due to substantial manufacturer rebates. Independent LTCPs typically obtain smaller rebates through group purchasing organizations, and thus focus on drug utilization management techniques.

Many State Medicaid programs have preferred drug lists that apply to both community-dwelling and institutionalized dual-eligibles. Federal protections ensure timely access to non-preferred drugs when medically necessary. Specifically, States must respond to requests for exceptions or prior authorization within 24 hours, they must reimburse the pharmacy for dispensing a 72-hour emergency supply, and they must have a mechanism for appeal of denial. Most Medicaid programs cover benzodiazepines, as well as some OTC drugs. For Medicare Part A residents, NFs are at risk for total drug costs, so have a financial incentive to use less-expensive OTCs. Commercial payers generally do not cover OTCs, except occasionally as part of a step therapy program.

Plans of the Secretary

Section 107(b) of MMA requires a description of the plans of the Secretary to implement Part D, in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of LTC facility patients. On January 28, 2005, CMS published the Final Rule implementing Title I (CMS-4068-F) and creating Part D plans (42 CFR Part 423). Taken together, the Final Rule and pertinent guidance materials constitute the plans of the Secretary, which are designed (a) to ensure the ongoing safety of LTC facility patients, consistent with applicable laws, (b) to encourage drug manufacturer rebate savings to be passed on to the patient, and (c) to reduce incentives for over-utilization that may exist when consultant pharmacists are not independent from the pharmacy. Part D plans may be stand-alone prescription drug plans (PDPs) or Medicare Advantage plans offering prescription drug benefits (MA-PDs; 42 CFR §423.4). LTC facilities include (a) SNFs as defined under Title XVIII of the Social Security Act (SSA) and (b) NFs or medical institutions for which Medicaid makes payment throughout a month as defined under Title XIX of the SSA (42 CFR §423.100). In addition to NFs and SNFs, this definition includes intermediate care facilities for the mentally retarded and inpatient psychiatric hospitals (Final Rule Preamble II.C.1.c.), thus going beyond the definition used for the study conducted of current standards of practice in NFs.

The LTCP industry and Medicare beneficiaries residing in LTC facilities will be affected in several ways by Part D. Most importantly, the LTCP payer mix will shift from predominantly Medicaid to predominantly Medicare Part D. Therefore, coverage and formulary decisions will be made by Part D plans and CMS rather than by Medicaid and LTCPs (42 CFR §423.120(b)), dual-eligibles will have drug coverage under Medicare Part D instead of under Medicaid, and a much larger proportion of LTCP reimbursement will be negotiated rather than determined legislatively. Also, beneficiaries will be faced with the new task of choosing a Part D plan.

Finally, Part D allowable drug costs do not include some of the specialized consultant pharmacist and other non-dispensing services offered by LTCPs that are currently bundled into LTC pharmacy rates. Specifically, Part D payments to LTCPs may cover only drug ingredient and dispensing fees (42 CFR §423.100). Therefore, LTC facilities will need to obtain those specialized services through separate competitive contracts, either with a LTCP or with another source. Of particular interest, when Part D plans provide medication therapy management services (of the sort that may be similar to those currently provided to LTC facility residents by consultant pharmacists) for some chronically-ill high-use beneficiaries (42 CFR §423.153(d)), they must separate payment for those services from payment for drug ingredient and dispensing fees. Given all these changes, following is a summary of the plans of the Secretary to implement Part D in LTC facilities.

On January 21, 2005 (revised March 9, 2005), CMS released 2006 Part D plan application submission materials (posted at www.cms.hhs.gov/pdps/mpdbappmatrls.asp), and on March 16, 2005, CMS released a LTC guidance document and a transition process guidance document (both posted at www.cms.hhs.gov/pdps/specguidncmaterials.asp). Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC network, as long as the pharmacy is prepared to comply with relevant State laws and to meet certain performance and service criteria (42 CFR §423.120(a)(5)), based on widely used best practices in the market today, and provided the pharmacy is able to reach agreement with the Part D plan on all contracting terms and conditions, including payment rates. These criteria will be a required feature of contracts for all network LTC pharmacies—(1) comprehensive inventory and inventory capacity, (2) pharmacy operations and prescription orders, (3) special packaging, (4) intravenous medications, (5) compounding or alternative forms of drug composition, (6) pharmacist on-call service, (7) delivery service, (8) emergency boxes, (9) emergency log books, and (10) miscellaneous reports, forms, and prescription ordering supplies (LTC guidance, 3/16/05). The non-drug portions of these elements would represent legitimate costs to reflect in the dispensing fee.

Part D plans will be required to demonstrate that they have a network of participating pharmacies that provides convenient LTCP access to Part D enrollees who are LTC facility residents (42 CFR §423.120(a)(5)). Each plan will be required to demonstrate that its LTCP network ensures that beneficiaries in its service area who are or become institutionalized can routinely receive their Part D benefits without relying on the out-of-network provision (42 CFR §423.124(c)). To assist applicant plans in their strategic planning and contract negotiations with LTCPs, on February 17, 2005, CMS released a list of all LTC facilities (posted at www.cms.hhs.gov/pdps/mpdbappmatrls.asp). In addition, on April, 12, 2005, CMS posted an initial list of parties interested in contracting with Part D applicants (posted at www.cms.hhs.gov/pdps/intrstd3rdprtyinfo.asp and updated on June 7, 2005), which included a list of pharmacies interested in participating in LTCP networks, and is continuing to explore ways to further develop this pharmacy list.

To ensure access to medically necessary drugs for LTC facility residents, a Part D plan may include those key drugs in the formulary for all Part D enrollees, or may provide exceptions processes that will not discourage enrollment by beneficiaries who are or anticipate being LTC facility residents (LTC guidance, 3/16/05). Also, CMS will provide a special enrollment period

for beneficiaries entering in, living in, or leaving an institution, and an unlimited open enrollment period for beneficiaries enrolled in an MA-PD (42 CFR §423.38(c)(8)(ii)). Finally, by statute (MMA 1860D-14(a)(1)(D)(i)), institutionalized full-benefit dual-eligibles, who constitute approximately half of Medicare beneficiaries residing in LTC facilities, will be totally exempt from any cost sharing (42 CFR §423.782(a)(2)(ii)).

To ensure access during the transition, CMS is working with States and the Social Security Administration to facilitate auto-enrollment of dual-eligibles by mid-October. Part D plans will be required to establish an appropriate transition process for new enrollees who are transitioning from Medicaid or other prescription drug coverage and whose current drug therapies may not be included in their Part D plan's formulary, taking into account the unique needs of LTC facility residents (42 CFR §423.120(b)(3); transition process guidance, 3/16/05). Specifically, CMS suggests that a "first fill" for 90-180 days may be appropriate for LTC facility residents, as they make multiple medication transitions (transition process guidance, 3/16/05). In addition, on May 11, 2005, CMS released a transition plan for dual-eligibles that outlines a Fall 2005 education and outreach campaign that will include providing support to LTCP stakeholders assisting LTC facility residents and family caregivers (posted at www.cms.hhs.gov/medicarereform/lir.asp).

There is special interest in access to select OTCs (e.g., Prilosec® and Claritin®, which were available by prescription when first marketed), and for LTC facility residents, to benzodiazepines as well, both of which are excluded under Part D (MMA 1860D-2(e)(2)). For dual-eligibles, benzodiazepines and OTCs must continue to be covered by Medicaid, unless a State specifically chooses to eliminate such coverage for all its Medicaid recipients. On June 3, 2005, CMS released a guidance letter to State Medicaid Directors encouraging States to continue to cover benzodiazepines for dual-eligibles (posted at www.cms.hhs.gov/states/letters), for which States would receive a Federal match, and emphasizing that coverage cannot be eliminated only for certain subgroups of Medicaid recipients (Title XIX of the SSA). Although some other beneficiaries may receive coverage for benzodiazepines under a supplemental Part D benefit package (42 CFR §423.104(f)(1)(ii)(A)), OTCs cannot be covered in this way because they do not require a prescription. On April 6, 2005, CMS released OTC guidance informing plans that, for OTCs that are part of specific step therapy protocols designed to control costs, they may include those costs in the administrative costs of their mandatory drug utilization management program, at no cost to the beneficiary (posted as a response to a frequently asked coverage/formulary question at www.cms.hhs.gov/medicarereform/drugcoveragefaqs.asp).

Plans must make a coverage determination as quickly as the enrollee's health condition requires, and no later than 72 hours following the request (42 CFR §423.568(a)). To ensure that LTC facility residents receive quick determinations from plans regarding medically necessary drugs, CMS is encouraging plans to consider the special circumstances of these beneficiaries when making coverage determinations, including applicable laws and regulations affecting the LTC facility and relationships among the facility, pharmacy, and physician (LTC guidance, 3/16/05). Furthermore, on June 2, 2005, CMS released an emergency coverage guidance document specifying that plans will be required to provide a one-time emergency supply while processing coverage determinations for LTC facility residents (posted at www.cms.hhs.gov/pdps/specguidncmaterials.asp).

Per longstanding industry practice, each LTC facility can choose to continue to contract exclusively with one LTCP, or can choose to contract with more than one LTCP. However, for patient safety and efficiency, facilities will likely want to minimize the number of pharmacy providers. To ensure Part D benefit access to the maximum number of its Medicare beneficiary residents, while at the same time minimizing the number of pharmacies with which it contracts, facilities will have an incentive to select pharmacies that contract with a large number of Part D plans. Therefore, pharmacies will have incentives to meet the Part D performance and service criteria, to contract with multiple Part D plans for competitive reimbursement rates, and to offer specialized LTCP services to NFs at competitive prices.

Given that Part D plans will likely have variations in their formularies and reimbursement rates, CMS will provide support to LTC facilities so that they can make informed choices for LTC pharmacy services and find the best fit for their operational needs. This includes making available information on all pharmacies able to serve the facility that meet the Part D performance and service criteria, and on the Part D plans with which those pharmacies contract. Beneficiary enrollees can appoint a representative authorized to act on his or her behalf (42 CFR §423.560). CMS also expects to provide plan-level information regarding prices for covered drugs and pharmacy network that beneficiaries and their representatives can use, particularly the most important information for a LTC resident, that is, which Part D plans provide access to pharmacy services in the facility in which the beneficiary resides.

On April 4, 2005, CMS released the final 2006 Part D plan payment methodology (posted at www.cms.hhs.gov/healthplans/rates). Plan payment will be risk adjusted for characteristics of that plan's enrollees. The basic payment model is based on a regression analysis that used demographic and diagnostic variables to predict prescription drug plan liability under the standard Part D benefit among community-dwelling beneficiaries enrolled in FFS Medicare. The incremental dollars associated with each variable in the model are divided by the mean predicted dollars to produce a risk factor for that variable. An individual beneficiary's risk adjustment factor is the sum of that individual's risk factors, and the individualized capitation rate is the product of the individual's risk adjustment factor and the plan bid, adjusted for the premium.

This basic model excluded two groups for which special additional adjustments were developed—beneficiaries eligible for the low-income (LI) subsidy and LTC beneficiaries. LTC status is defined as residing in a NF for more than 90 days prior to the payment month. The LTC adjustment factor represents the proportion by which actual spending by institutionalized beneficiaries exceeds spending predicted by the basic model. For aged institutionalized beneficiaries (i.e., those eligible for Medicare because they are 65 years or older), the adjustment factor is 1.08, and for disabled institutionalized beneficiaries (i.e., those eligible due to disability), the adjustment factor is 1.21 (payment methodology, 4/4/05). The LI adjustment factor was developed exclusively for community-dwelling LI beneficiaries, and the LTC adjustment factors were developed exclusively for LTC beneficiaries, regardless of income status. Therefore, the LI adjustment factor cannot be applied to institutionalized beneficiaries. That is, only the pertinent LTC adjustment factor, aged or disabled, will be applied. This adjustment ensures that payment to Part D plans is appropriately adjusted for the institutionalized beneficiaries they serve.

Recommendations of the Secretary

Section 107(b) requires the Secretary to provide recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to Medicare beneficiaries residing in LTC facilities, in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

The plans of the Secretary address the reimbursement and patient safety issues raised by the study conducted by CMS of current financing and delivery standards of practice. Consequently, the Secretary has no legislative recommendations at this time. However, given that Part D is a new program, it will be essential to monitor broadly early experiences with implementation. Specific issues to monitor carefully include (1) the degree to which LTC facilities will influence beneficiary plan choice and the ease with which beneficiaries make that choice, (2) the impact of Part D formularies on current drug regimens of beneficiaries and the smoothness of the transition to Part D, (3) whether LTC facilities will have to change LTCPs or work with multiple pharmacies, and if so, the impact of this shift from the one-to-one model, (4) the effectiveness with which LTC facilities and LTCPs manage multiple formularies, (5) the effectiveness with which plans manage the benefit in the LTC setting, (6) the effectiveness with which plans control drug costs for beneficiaries, (7) the financial impact on LTC facilities and LTCPs, (8) whether there will be increased competition among LTCPs, and (9) the degree to which LTCPs or Part D plans will have greater negotiating leverage. If necessary, the Secretary will make recommendations for actions based upon the implementation and early operational experiences of the Part D program.