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Oversight and Enforcement of Medicare Part D Plan Requirements: Federal Role and Responsibilities

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INTRODUCTION

On January 1, 2006, Medicare began to cover prescription drugs through a new voluntary and privately-administered Part D program, established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[1] To obtain prescription drug coverage, Medicare beneficiaries must take the affirmative step of enrolling in a private Medicare Part D plan that is either a stand-alone prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD).

Plan flexibility is a guiding principle of the regulations implementing the MMA. The Centers for Medicare & Medicaid Services (CMS) described this flexibility in the preamble to the final regulations: "The goal of the MMA was to encourage private sector organizations who meet the law's requirements to offer a range of Part D plan options for Medicare beneficiaries by providing flexibility in plan design and management."[2] The MMA and final regulations[3] give PDPs and MA-PDs broad discretion to decide which specific drugs to include in their formularies, the strengths and dosage forms of covered drugs, and the types of "utilization management processes" to use.[4] Each PDP and MA-PD also has authority under the MMA to establish its own exceptions[5] and appeals[6] procedures. The preamble to the final regulations also acknowledges that CMS would issue further "operational guidance" to plans with specific suggestions for plan activities relating to Part D implementation.[7] To date, CMS has issued informal sub-regulatory guidance to plan sponsors on the transition process,[8] long-term care,[9] marketing,[10] and other areas.

This Issue Brief, commissioned by the Kaiser Family Foundation, presents legal advocates' views and analysis of how CMS and the U.S. Department of Health and Human Services Office of Inspector General (OIG) enforce compliance with requirements of the new Medicare Part D Prescription Drug benefit. The brief begins with a discussion of "potential schemes, risks, and vulnerabilities in the Part D benefit"[11] and then considers the authority given to OIG and to CMS by law, regulation, and contract to enforce Part D requirements. It turns next to CMS's "Part D Oversight Strategy" and interpretation of its authority, which methods CMS uses to determine plans' compliance with Part D requirements, whether CMS can enforce its informal guidance, and finally, whether and how CMS has used its enforcement authority.

PLAN REQUIREMENTS AND RESPONSIBILITIES IN IMPLEMETING MEDICARE PART D

The MMA final regulations give CMS authority to impose sanctions against plans for noncompliance with six categories of program requirements. Significantly, *harm to a single plan enrollee is sufficient, under the regulations, to justify and support the imposition of a sanction.* 42 C.F.R. §423.752(a)(1). The regulations authorize CMS to impose sanctions against a plan that:

- "fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee." 42 C.F.R. §423.752(a)(1);

- imposes premiums on enrollees "in excess of the monthly basic and supplemental beneficiary premiums permitted" by the law and regulations. §423.752(a)(2);

- "acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part." §423.752(a)(3);

- "engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services." §423.752(a)(4);

- "misrepresents or falsifies information" that it provides to CMS or to an individual or entity under the Part D program." §423.752(a)(5); or

- employs or contracts with an individual or entity that is barred from participating in Medicare. §423.752(a)(6).

Fraud, Waste, and Abuse Guidance (Chapter 9)

CMS uses the phrase "fraud, waste and abuse" (FWA) to characterize violations of Part D requirements beyond compliance issues. In guidance to plan sponsors on programs to control FWA, CMS identifies a number of "potential risks areas" in Part D that are applicable to plan sponsors, pharmacy benefit managers, pharmacies, prescribers, wholesalers, pharmaceutical manufacturers, and beneficiaries.[12] Potential risk areas for plan sponsors include many Part D practices that directly affect enrollees:[13]

- *Failure to provide medically necessary services* to an enrollee that the plan is required, by law or contract, to provide and the failure does, or is substantially likely to, adversely affect the enrollee;

- *Marketing schemes* (e.g., enrolling a beneficiary without the beneficiary's knowledge or consent; enrolling a beneficiary in an MA-PD when the beneficiary wanted to enroll in a PDP);

- *Payments for excluded drugs;*

- *Multiple billing* (billing Parts A or B and D for the same prescription drug);

- *Non-compendium payments* (paying for drugs under Part D that are not for a "medically accepted indication");

- *Inappropriate formulary decisions (*e.g., giving costs priority over clinical efficacy and appropriateness in making formulary decisions);

- *Inappropriate enrollment*/*disenrollment* (e.g., failing to disenroll a beneficiary who requests disenrollment);

- *Appeals process handled incorrectly* ("Medicare beneficiary denied their right to appeal or denied a timely appeal.");

- *Adverse selection* ("selecting or denying beneficiaries" based on prohibited discriminatory factors, such as their "illness profile," in order to avoid beneficiaries with "many or severe comorbid diseases");

- *False information* ("Plan misrepresents or falsifies information it furnishes to CMS or to an individual under the Part D drug benefit program.");

- *Delinquent reimbursement* ("Beneficiary is not reimbursed by the plan following retroactive low income subsidy determination.");

- *Duplicative premiums* ("Receiving duplicative co-pays or premiums from beneficiaries");

- *Excessive premiums* ("Impose on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under the regulation.");

- *Incorrect calculation of TrOOP* (true out-of-pocket) to keep the beneficiary in the coverage gap or to "push" beneficiaries through the gap; and

- *Bait and switch pricing* ("frequent formulary changes to induce beneficiaries to sign up for specific drugs that are later removed.")

The extent to which these practices may be occurring is unknown, but news media reports suggest that some violations have occurred. *Business Week,* for example, reported in January 2006 that Humana initiated an "enroll and migrate" plan to switch Part D enrollees into MA-PD plans and was paying its sales staff commissions for MA-PDs enrollments that were more than double the commissions for PDPs.[14] The Kaiser Family Foundation's focus group with Medicare State Health Insurance Assistance Program (SHIP) Directors in June 2006 continued to report plans' aggressive marketing practices that drive beneficiaries to Medicare Advantage plans.[15] Focus group members also identified plans' "imposing complicated prior authorization requirements as a means to encourage sicker enrollees to move to other plans."

Sub-regulatory Guidance

Both before and after the Medicare prescription drug benefit went into effect on January 1, 2006, CMS provided extensive sub-regulatory guidance to Part D plan sponsors, issued as memoranda to plan sponsors, frequently-asked questions and answers, and other informal oral and written communications. Through some of its guidance issuances, CMS has sought to clarify its policies. Other guidance documents contradict, and purport to change, regulatory standards, thus eliminating or reducing the flexibility described in the regulations.

An example of CMS's sub-regulatory guidance in 2006 is efforts to spur plan compliance when many Medicare beneficiaries were not getting the prescription drugs they needed during the initial transition to Part D. CMS wrote to "All Part D Sponsors" on January 6, 2006, reminding them of "transition policy requirements that must be upheld" and of the need to ensure that beneficiaries get prescription drugs without delay, denial, or undue burden.[16] When problems with transition to Part D plans continued after CMS issued its clarifying guidance, CMS Administrator Mark McClellan wrote to prescription drug plans again, on February 2, 2006. Contradicting the regulations,[17] which allow plans to establish their own transition periods, he "called for" "a one-time across the board extension of the transition period" through March 31, 2006 for beneficiaries who had enrolled in the first few months of the program.[18] Then, on March 17, 2006, just before the new three-month transition period was about to end, CMS revised its guidance once again. It now reminded plans that transition is a process, not a date, and that plans should use "sound judgment to extend that temporary coverage in certain situations in which a longer transition may be required for valid medical reasons."[19]

In another example of sub-regulatory guidance, on April 27, 2006, CMS sent a memorandum to Part D plan sponsors suggesting that they exempt plan enrollees from formulary changes made during the contract year.[20] This guidance contradicts the final regulations, which give plans discretion to change formularies during a plan year after giving appropriate notice.[21] (Indeed, the preamble to the final regulations explicitly confirmed CMS's position that the agency lacked authority "to preclude mid-year changes to a Part D plan's formulary list."[22]) However, the memorandum purports to change the final regulations, stating that CMS "expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts."[23]

AUTHORITY TO ENFORCE PART D REQUIREMENTS

Authority to enforce Part D statutory and regulatory requirements is shared by CMS and HHS' Office of Inspector General.

CMS's Enforcement Authority

CMS's authority to enforce the MMA depends on the language of the law and regulations as well as the contracts that CMS signs with plan sponsors. The MMA largely incorporates the enforcement scheme and provisions that apply to managed care organizations under Medicare Part C.[24] The final regulations address the sanctions that CMS may impose as well as the process for imposing them.

The Contract between CMS and Part D Plans

Each entity that wants to participate in Part D as a sponsor for one or more plans must apply to CMS for a determination that it is qualified.[25] If found qualified and approved to be a plan sponsor and then, if successful in negotiating a bid with CMS, the entity signs a contract with CMS.[26] Among the conditions necessary to contract with CMS, an entity must have a compliance plan that includes written policies and procedures, a commitment to comply with "all applicable Federal and State standards," designation of a compliance officer and committee, procedures for internal monitoring and auditing of compliance, and procedures to respond to "detected offenses and development of corrective action initiatives."[27]

The lengthy regulation on contract provisions obligates each plan sponsor to agree to "All the applicable requirements and conditions set forth in this part and in general instructions"[28] as well as 17 specified regulatory standards.[29] In addition, plan sponsors agree to communicate electronically with CMS,[30] maintain records for 10 years,[31] provide access to facilities and records to HHS and the Comptroller General,[32] disclose information to CMS and beneficiaries,[33] comply with beneficiary financial protections,[34] and comply with requirements of other laws and regulations.[35]

Under the terms of the contract, PDP sponsors agree to comply with the law and regulations and any changes required by law or regulations "or policies implementing or interpreting such statutory provisions."[36] Sponsors agree to develop and implement a compliance plan, as set out in the regulations.[37] CMS agrees in the contract that "it will not implement, other than at the beginning of a calendar year, regulations under 42 CFR Part 423 that impose new, significant regulatory requirements on the PDP Sponsor."[38]

Enforceability of Sub-regulatory Guidance

Whether CMS can legally enforce the informal guidance that it has frequently sent plan sponsors depends on (1) whether the guidance is consistent with the law and regulations or (2) whether plans agreed, by contract, to comply with all guidance issued by CMS during the plan year, or both. While plan sponsors agree, by contract, to comply with CMS's "general instructions," the regulations expressly prohibit CMS from implementing, "other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan."[39] Consequently, it is unlikely that CMS can directly enforce the

informal *sub-regulatory* guidance given to plan sponsors in 2006 that creates "new, significant" requirements.

CMS's early sub-regulatory guidance to Part D plans used language that made clear its non-binding nature. CMS "suggested" or "encouraged" plans to take certain actions, but left plans with considerable flexibility to accept or reject CMS's advice. Chapter 9 of the Prescription Drug Benefit Manual makes clear the non-binding nature of guidance using such language: "Finally, it should be noted that recommendations made in this chapter are reflected by the use of the term "should," whereas statutory or regulatory program requirements are reflected by the use of the term 'shall' or 'must.'"[40]

CMS's more recent sub-regulatory guidance removes plan flexibility and purports to impose "new" and "significant" obligations on plan sponsors – for example, mandating a 90-day transition period and grandfathering enrollees into formularies that plans change for new enrollees. Guidance of this nature would likely be unenforceable by CMS because, as a matter of administrative law, any guidance that imposes new and binding legal obligations on regulated entities is a legislative rule. A legislative rule is subject to notice and comment rule-making under the Administrative Procedure Act in order to be enforceable.[41] CMS may not enforce, as binding requirements, documents that have not been properly promulgated as regulations.

OIG's Enforcement Authority

The Department of Health and Human Services' Office of Inspector General has authority to impose civil money penalties for violations described in §423.752(a) or for violations under §423.509(a) involving fraudulent or abusive activities in addition to, or instead of, sanctions imposed by CMS. §423.756(f)(2). Although OIG issued interim final regulations[42] and final regulations[43] for the Medicare Part D prescription drug card, it has not issued regulations for the prescription drug benefit. It is unclear whether OIG can impose civil money penalties for violation of Part D requirements.

In addition to imposing civil money penalties, OIG has authority to issue Special Advisory Opinions that alert the health care industry about potential problems or issues of interest. OIG issued a Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees.[44] OIG may also issue Advisory Opinions on specific proposed actions and has issued three on Part D issues: one on a pharmaceutical assistance program's providing free drugs,[45] a second, on a charitable corporation's provision of premium and cost-sharing assistance to needy Medicare beneficiaries,[46] and a third, on a charitable organization's subsidizing Medicare Part D premium and cost-sharing obligations for financially needy beneficiaries with end-stage renal disease and chronic kidney disease.[47]

Finally, OIG issues reports on audits as well as evaluations and inspections. OIG's *Work Plan Fiscal Year 2006* identifies 19 reports that it will issue on the administration of Medicare Part D, including such issues as marketing materials, fluctuation in drug prices, plans' use of formularies, and plans' implementation of required programs to

deter fraud, waste, and abuse.[48] Since the start of 2006, OIG has issued one report evaluating the extent to which Medicare prescription drug plan formularies include drugs commonly used by dual eligibles under Medicaid.[49]

IMPOSING SANCTIONS

The final rules establish that CMS has authority to impose a variety of sanctions for plan violations of MMA's statutory and regulatory requirements. However, it is not required to impose them. The sanctions include:

- civil money penalties, ranging from $10,000 to $100,000;
- suspension of enrollment of Medicare beneficiaries;
- suspension of Medicare payments to Part D sponsors; and
- suspension of plan marketing activities. [42 C.F.R. §423.750(a)(1)-(4).]

Before imposing any sanction, CMS must first give the Part D sponsor written notice stating "the nature and basis of the proposed sanction." §423.756(a)(1)(i). CMS also must notify the Office of Inspector General (OIG), §423.756(a)(1)(ii). OIG has authority to impose civil money penalties in addition to, or instead of, those imposed by CMS. §423.756(f)(2).

CMS must give the Part D sponsor 15 days after receiving the notice (with the possibility of an additional 15 days) to respond to the notice and "to provide evidence that it has not committed an act or failed to comply with the requirements described in §423.752, as applicable." §423.756(a)(2).

A CMS official who did not participate in the initial decision to impose a sanction then conducts an "informal reconsideration" and gives the Part D sponsor "a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination." §423.756(b)(1) and (2).

If CMS affirms the initial finding of a violation of program requirements, it may

- "require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period." §423.756(c)(1);
- "suspend payments to the Part D sponsor for Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period," if the violation involves the imposition of excess premiums. §423.756(c)(2);

- "require the Part D sponsor to suspend all marketing activities for the sanctioned plan during the sanction period." §423.756(c)(3);

- decline to renew a contract, as described at §423.507. §423.756(e);

- terminate a contract, as described at §423.509. §423.756(e);

- impose civil money penalties, if the violation involved the imposition of excess premiums (§423.752(b)), other than a determination of fraud and abuse under §423.509(a)(4)). §423.756(f)(3).

CMS may impose a maximum civil money penalty of $25,000 for a violation that adversely affects an enrollee or has a "substantial likelihood" of adversely affecting an enrollee. §423.758(b). Uncorrected deficiencies are subject to a maximum civil money penalty of $10,000 per week. §423.758(c). If a Part D sponsor terminates its contract with CMS, but does not follow the requirements for contract termination (§423.510), CMS may impose a civil money penalty of $250 per enrollee or $100,000, whichever is greater. §423.758(c).

CMS has retained full discretion to impose one or more sanctions as it deemed appropriate, declining commenters' request to provide a methodology for determining when to impose specific remedies. 70 Fed. Reg. 4193, 4366 (Jan. 28, 2005) (preamble to final regulations). Sanctions imposed by CMS become effective 15 days after the plan sponsor is notified of the decision, §423.756(d)(1), and remain in effect until CMS notifies the plan sponsor that "CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur." §423.756(d)(3). A sanction may become effective at an earlier date if the sponsor's conduct "poses a serious threat to an enrollee's health and safety." §423.756(d)(2).

PROCEDURES FOR OVERSIGHT AND MONITORING OF PLAN ACTIVITY

Although the regulations give CMS broad authority to enforce Part D requirements, CMS appears to view its enforcement role narrowly. CMS gives plan sponsors considerable authority to monitor and correct their own behavior, as well as the behavior of those they contract with, and has said that it will work with plans on day-to-day compliance issues and limit its civil enforcement activities to "large, repeat and/or egregious" violations.[50] CMS also takes a broad view of federal pre-emption, announcing that all state laws, other than those related to state licensure and state solvency, are pre-empted by the MMA. As an example, CMS contends that marketing materials approved by CMS may not be challenged as violating state law.[51]

Reliance on Plans to Self-Monitor Compliance with MMA Law and Regulations

Each plan sponsor must have a comprehensive plan "to detect, correct, and prevent fraud, waste, and abuse," including "procedures to voluntarily self-report potential fraud

or misconduct related to the Part D program to the appropriate government authority."[52] The plan must include "enforcement of standards through well-publicized disciplinary guidelines."[53] CMS encourages, but does not require, plan sponsors to have a complaint tracking system for "customer" complaints and to make the complaint log available to CMS on request.[54] It also suggests that plan sponsors consider having an internal audit department[55] and use data analysis[56] and other monitoring and oversight efforts.[57] The expectation is that plan sponsors will prevent or identify and correct their own violations.

CMS's Part D Oversight Strategy

CMS's oversight of Part D sponsors' compliance with requirements occurs in three ways: resolution of day-to-day compliance issues, civil enforcement of "large, repeat and/or egregious Part D program violations," and referral of suspected instances of fraud, abuse, and waste to law enforcement agencies for further review and, as appropriate, prosecution. According to CMS, the agency's oversight goals are "to identify Part D program vulnerabilities, assure strict adherence to Part D regulatory and program requirements, and detect and prevent fraud, waste, and abuse."[58]

CMS's primary methods of gathering information about plans' compliance or noncompliance with Part D requirements are 1) monitoring data submitted by plans, 2) conducting audits, and 3) beneficiary complaints.

1) Monitoring

Plans are required to submit data on a variety of topics to CMS. Reporting requirements for 2006 include enrollment/disenrollment; claim reversals; medication therapy management programs; generic dispensing rate; grievances; prior authorization, step edits, non-formulary exceptions, and tier exceptions; appeals; call center measures; overpayment; pharmaceutical manufacturer rebates, discounts, and other price concessions; and licensure and solvency, business transactions and financial requirements.[59] Guidance documents for "formulary, TrOOP, coordination of benefits, payment and 1/3 audit, employer subsidy, low income subsidy, and Fallbacks" include additional reporting requirements for plan sponsors.[60]

CMS receives data from plans on these issues and "will develop reports and related intervention metrics to serve as the triggers to ad hoc data mining and reporting."[61] In the area of Performance Measures, for example, CMS will generate reports for Appeals, Enrollment/Disenrollment, Generic dispensing rate, Medication Therapy Management, Rebates, and Prior Authorization/Step Edits/Non-Formulary Exceptions.[62]

Other data systems for contractor management activity are Utilization Management, Medication Adherence and Persistence, Quality Assurance, Coverage Determination, Complaint Tracking, and Long-Term Care Pharmacy Access.[63]

2) Audits
CMS conducts financial audits of at least one-third of Part D sponsors each year.[64] These audits are "randomized desk audits"[65] – that is, audits conducted at the auditor's office, without an on-site visit to the plan. In addition, CMS may conduct an on-site audit at any time to determine compliance with the contract or Part D regulatory requirements.[66] Focused or targeted audits are conducted "when questionable findings are identified through contractor management activities, such as data analysis or analysis of appeals, grievance and complaint data."[67] Audits are also conducted by CMS's Office of Financial Management (OFM) and the MEDIC in instances of allegations of fraud, waste or abuse.[68]

3) Beneficiary Complaints
CMS reports that it intends to receive information from beneficiaries about plan sponsors' compliance with Part D requirements from both plan sponsors' consumer satisfaction surveys and "a nationwide complaints tracking system."[69] The regulations state, without elaboration, only that "CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under §422.152(b) of this chapter."[70] The "nationwide complaint tracking system" is not described in the regulations.

On March 29, 2006, CMS confirmed that it refers complaints that it receives on 1-800-Medicare to Part D plans and that plans are expected to resolve them. In a memorandum to All Part D Sponsors announcing plans to improve the complaint resolution process (by uploading complaints to a Complaint Tracking Module (CTM) and giving plans direct access to CTM), CMS stated that plans resolve complaints and that CMS, through Regional Office caseworkers, will "review the Plan notes and ensure resolution is satisfactory prior to officially closing the case."[71]

CMS's Internal Oversight Structure

CMS divides its oversight and enforcement authority among various CMS components: CMS's Center for Beneficiary Choices (CBC) and CMS's Regional Offices are responsible for "operational oversight issues" and CMS's Office of Financial Management (OFM) is responsible for "preventing, identifying, and addressing fraud, waste and abuse."[72] In addition, CMS works with private program integrity contractors, called Medicare Drug Integrity Contractors (MEDICs), which assist CMS in all oversight functions. MEDICs oversee compliance and also perform data analysis for fraud, waste, and abuse identification.[73] CMS explicitly modeled its oversight of Part D plans on its oversight of Medicare Advantage organizations.

CMS intends that account managers assigned to each plan in CMS's central and Regional Offices review the self-reported, unaudited data that plan sponsors submit to CMS.[74] Account managers also resolve day-to-day compliance issues, coordinate audits, and refer "large, repeat and/or egregious Part D program violations" to the CBC Medicare Plan Accountability Group (MPAG). They refer suspected fraud, abuse, and waste to OFM or the appropriate MEDICs, or both. CMS has yet to issue task orders to

seven of eight MEDICs that CMS said in October 2005 would be assigned responsibility for program integrity activities.[75] However, CMS recently stated it intends to award the remaining MEDIC contract awards by the end of September 2006.[76]

Disclosure of Enforcement Activity

CMS has stated that it does not intend to disclose the compliance status of Part D plans. In the preamble to the final regulations, CMS explained its reasoning:

> Some organizations that have received sanctions have later become solid examples of compliant contract administration. We believe that a public listing of sanctioned Part D Plans may not portray the current level of compliance by contracted organizations and could unfairly impede business opportunities for fully compliant contractors that were sanctioned in prior years. The purpose of a sanction is to protect beneficiaries and public funds by improving the compliance of contracted organizations. When an organization resumes compliant behavior, the sanction is ended. Sanction authority is not designed to be punitive.

70 Fed. Reg., 4367. However, plans' corrective action plans are subject to disclosure under the Freedom of Information Act. *Id.* 70 Fed. Reg., 4367.

ENFORCEMENT ACTIVITY IN 2006

The frequent revisions to guidance and regulations governing Part D sponsor activity indicate recognition of problems and concerns with implementation of the Part D benefit since the start of 2006. On March 10, 2006, Dr. McClellan sent a memorandum to "All Part D Sponsors" describing four major areas that CMS has discussed with plans "where many plans can continue to improve performance."[77] The areas are:

- "effective data systems" to "handle near real-time data processing" for updating enrollment and co-payment data, prompt resolution of eligibility and copay status, and information for pharmacists;

- "effective exceptions and appeals," including compliance with transition guidance, using "consistent forms" for exceptions and prior authorization processes, and "consistent code responses when edits apply in pharmacy transactions;"

- "strong relationships with pharmacists;" and

- "effective customer service" to "provide timely and effective responses to inquiries from members, pharmacies, physicians, and other professionals."

The comprehensive nature of this list indicates CMS's awareness of the difficulties experienced by many beneficiaries with initial implementation of the Part D benefit. The

memorandum indicates that CMS has discussed these issues privately with plans. CMS has also attempted to address some of these areas through sub-regulatory guidance.

In a May 3, 2006 letter to Representative Pete Stark, CMS Administrator McClellan wrote that CMS was "continuing its longstanding compliance and enforcement activities." Specifically with respect to Part D, he wrote:

> In 2005, for example, CMS used the full range of enforcement tools available to us. This includes issuing numerous corrective action plans and compliance warning letters. Usually, these steps lead to responsive actions promptly by plans. However, where necessary to get compliance, we also levied civil monetary penalties and implemented intermediate sanctions freezing marketing and enrollment. Where necessary, we will also terminate plans. Based on our monitoring in all of the areas described – like pricing, and formulary and prior authorization implementation, and other areas – we will continue to use all these tools for our oversight of the drug benefit as well.[78]

Although CMS stated in the preamble to the final regulations that it would not publicly release ongoing information about plans' compliance status, it released information five days after *The New York Times* reported that "the Bush administration is having difficulty regulating [Medicare drug] plans to ensure they comply with federal standards for marketing, customer service and consumer protection."[79] On June 29, 2006, CMS issued a press release that outlined "more than 1,000 compliance actions to improve prescription drug plan service to beneficiaries" – "651 warning letters to plans," "152 notices of non-compliance," and "318 requests for specific business plans."[80] Of these 1,000-plus compliance actions, few are enforcement actions as defined in the regulations (*e.g.*, civil penalties, bans on marketing). "Warning letters" and "notices of non-compliance" are written notices that are required by the regulations *before* any enforcement can occur. CMS's news release indicates that, at most, CMS imposed one corrective action plan and has taken steps towards termination of one other plan.

Whether CMS advised any plan sponsor by the May 1 deadline that it is ineligible to renew its contract[81] for 2007 is unknown. Information about such non-renewals will not be disclosed to plan enrollees and the general public until 90 days before the end of the current plan year (October 1).[82]

POLICY OPTIONS

- CMS could make publicly available reports and information about plans' compliance with Part D requirements. Information could address such issues as complaints (numbers, resolution), formulary changes (numbers and types), exceptions (requested and granted), appeals (numbers and outcomes), and customer service. Information could be reported nationally as well as specifically for each plan on a monthly basis as well as just prior to the annual open enrollment period.

- CMS could make publicly available reports and information about CMS' enforcement activity. Information could identify, by plan, any sanction imposed, including the reason for the sanction, its duration, and other pertinent information. Information could also identify CMS's referrals to other civil and criminal enforcement agencies.

- CMS could investigate and resolve, directly or through an independent entity, complaints that beneficiaries make through 1-800-Medicare. CMS could both work with plans to resolve complaints for individual complainants and use complaints to identify systemic problems that require broader solutions. Assistance from CMS with beneficiary complaints could help to identify systemic patterns of violations and generate responsive, systemic changes to plans' activities.

- CMS could make readily available on the Medicare.gov website comprehensive enforcement information about Part D plans.

- Congress could amend the MMA to

    - establish mandatory penalties for violations, in addition to discretionary remedies, which would ensure that major violations of rules and guidelines are required to be sanctioned.

    - confirm that the MMA does not pre-empt state enforcement of state law violations.

    - authorize private enforcement of MMA requirements, which would mean that beneficiaries could file litigation on their own behalf to enforce the requirements of the MMA.

- OIG could promulgate regulations authorizing OIG to impose civil money penalties for violation of Part D requirements.

NOTES

[1] 42 U.S.C. §§1395w-101 through 1395w-152; Pub.L. 108-173 (Dec. 8, 2003).
[2] 70 Fed. Reg., at 4263. CMS said for example, "The amount of cost-sharing, and any variations in cost-sharing based on brands, generics, or other classifications will be determined by Part D plans." 70 Fed. Reg., at 4238.
[3] 42 C.F.R. Part 423; 70 Fed. Reg. 4193 (Jan. 28, 2005).
[4] Utilization management tools include *tiered pricing* (charging different co-payments for different drugs to distinguish among preferred drugs, non-preferred drugs, and generic drugs), *prior authorization* for covered prescription drugs, and *step therapy* (requiring that beneficiaries try drugs included in the plan's formulary before those prescribed by the physician).
[5] 42 C.F.R. §423.578. Plan enrollees may use their plan's exceptions process to pay a lower co-payment for a formulary drug, to get a non-formulary drug covered by the plan.
[6] 42 C.F.R. §423.560-.638. Appeals include various levels of review of adverse coverage determinations – redeterminations, reconsiderations by the Independent Review Entity, hearings by the Administrative Law Judge, review by the Medicare Appeals Council, and judicial review.
[7] For example, CMS said that it expected "to establish an exceptions process," which it would "outline in operational guidance to Part D plans." 70 Fed. Reg., at 4248.
[8] CMS, "Information for Part D Sponsors on Requirements for a Transition Process" (Mar. 16, 2005), http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/TransitionProcess_031605.pdf [hereinafter CMS, "Transition Process.].
[9] CMS, "Long Term Care Guidance" (Mar. 16, 2005), http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/LTCGuidance.pdf [hereinafter CMS, "LongTerm Care Guidance"].
[10] CMS, "Medicare Marketing Guidelines" (Aug. 15, 2005, rev. Nov. 1, 2005), http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/Marketing%20Guidelines%20Update.pdf [hereinafter CMS, "Marketing Guidelines"].
[11] CMS, Prescription Drug Benefit Manual; Chapter 9 – Part D Program to Control Fraud, Waste and Abuse, page 54 (Apr. 25, 2006), http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf [hereinafter CMS, Chapter 9].
[12] *Id.* section 70.
[13] Vulnerabilities for other "downstream" participants in Part D, such as pharmacies and drug manufacturers, describe more generic fraud and abuse issues that are less specifically and closely tied to Part D, such as a pharmacy's deliberately providing less than the prescribed quantity of drugs and charging for the full amount and a manufacturer's offering incentives to a physician to prescribe medically unnecessary drugs. *Id.* section 70, pages 57-62.
[14] "Plan A: Hook Them with Part D," *Business Week* (Jan. 30, 2006), http://www.businessweek.com/magazine/content/06_05/b3969093.htm.
[15] Julia James (Kaiser Family Foundation), "Early Experiences of Medicare Beneficiaries in Prescription Drug Plans; Insights from Medicare State Health Insurance Assistance Program (SHIP) Directors" (Aug. 2006), http://kff.org/medicare/upload/7552.pdf.
[16] CMS's letter reported that some plan customer service representatives were not aware of their plan's transition policies and, as a result, were incorrectly informing beneficiaries that they could get access to non-formulary drugs only by filing for an exception. CMS reminded Part D sponsors either to resolve prior authorization or step edit requirements at point-of-sale, generally by suppressing these edits during the transition period, or to provide beneficiaries with a temporary supply of formulary and non-formulary drugs. The guidance was fully consistent with regulatory requirements.
[17] 42 C.F.R. §423.120(b)(3) ("A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.").
[18] Mark McClellan, M.D. Ph.D., Administrator, CMS, "Extension of Transition Period to March 31" (Memorandum to Medicare Advantage Prescription Drug Plans and Medicare Prescription Drug Plans, Feb. 2, 2006), http://www.medicarerxguide.com/MDRG/2006/CMS_Transition_Extension.pdf.
[19] Gary Bailey, Deputy Director, Center for Beneficiary Choices, "Next Step on Formulary Transition Policies" (Memorandum to All Part D Sponsors, Mar. 17, 2006), http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoNextStepsonFormularyTransitionPolicies_03.17.06.pdf.
[20] Abby L. Block, Director, Center for Beneficiary Choices, "Formulary Changes During the Plan Year" (Memorandum to Part D Sponsors, Apr. 27, 2006), http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoFormularyChangeGuidance_04.27.06.pdf [hereinafter Block, "Formulary Changes"].
[21] 42 C.F.R. §423.120(b)(5).

[22] 70 Fed. Reg., at 4263.
[23] Block, "Formulary Changes," *supra* note 20, at page 3,.
[23] 42 C.F.R. §423.120(b)(5).
[24] 42 U.S.C. §1395w-112(b)(3)(E).
[25] 42 C.F.R. §423.502(a).
[26] *Id.* §423.504(a).
[27] *Id.* §423.504(b)(4)(vi) (compliance plan).
[28] *Id.* §423.505(b)(1).
[29] *Id.* §423.505(b)(2)-(18).
[30] *Id.* §423.505(c).
[31] *Id.* §423.505(d).
[32] *Id.* §423.505(e).
[33] *Id.* §423.505(f). Plans are required to "establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage." Information for beneficiaries that plans must submit to CMS includes "quality and performance data," including disenrollment rates, enrollee satisfaction, "recent records regarding compliance of the plan with requirements of this part," information about beneficiary appeals and their disposition, information about formulary exceptions, "information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization," and other information CMS may require about monitoring, oversight, and related matters. 42 C.F.R. §423.505(f)(2)(iv)(A)-(D).
[34] 42 C.F.R. §423.505(g), including protecting beneficiaries from incurring liability for fees that the Part D sponsor is legally obligated to pay.
[35] *Id.* §423.505(h).
[36] "Contract with Approved Entity Pursuant to Sections 1860D-1 through 1860D-42 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan," Article I.A.
[37] *Id.* Article II.K.
[38] *Id.* Article I.C.
[39] 42 C.F.R. §423.516.
[40] CMS, Chapter 9, *supra* note 11, at page 9.
[41] *General Electric v. EPA*, 290 F.2d 377, at 384 (D.C.Cir. 2002). *See also Sierra Club v. Mainella* __F.Supp.2d __, 2005 WL 3276264 (D.D.C. 2005); *Center for Auto Safety, Inc. v. National Highway Traffic Safety Administration*, 342 F.Supp.2d 1 (D.D.C. 2004).
[42] Interim Final Rule: OIG Civil Money Penalty Authority under the Medicare Prescription Drug Discount Card Program, 69 Fed. Reg. 28,842 (May 19, 2004), http://www.oig.hhs.gov/authorities/docs/04/051904drugdiscountcardCMPrulemaking.pdf.
[43] Final Rule, Civil Money Penalty Authority under the Medicare Prescription Drug Discount Card Program, 69 Fed. Reg. 74,451 (Dec. 14, 2004), http://www.oig.hhs.gov/authorities/docs/04/drug%20cardCMPfinal.pdf.
[44] 70 Fed. Reg. 70,623 (Nov. 22, 2005), http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf.
[45] OIG Advisory Opinion No. 06-03 (Apr. 18, 2006), http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf.
[46] OIG Advisory Opinion No. 06-04 (Apr. 20, 2006), http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-04A.pdf.
[47] OIG Advisory Opinion No. 06-09 (Aug. 18, 2006), http://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-09.pdf.
[48] OIG, Work Plan Fiscal Year 2006, http://oig.hhs.gov/publications/docs/workplan/2006/WorkPlanFY2006.pdf.
[49] OIG, Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs, OEI-05-06-00090 (Jan. 2006), http://oig.hhs.gov/oei/reports/oei-05-06-00090.pdf.
[50] CMS, "Part D Oversight Strategy" (Oct. 24, 2005), http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/OversightStrategy_10.24.05.pdf [hereinafter CMS, "Oversight Strategy"]..
[51] Frequently asked questions, #7241 (created May 12, 2006, updated May 16, 2006), http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=7241&p_created=1147438737&p_sid=XFgETO7i&p_accessibility=0&p_lva=6142&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MSZwX3Byb2RzPTAmcF9jYXRzPSZwX3B2PSZwX2N2PSZwX3NlYXJjaF90eXBlPWFuc3dlcnMuc2VhcmNoX25sJnBfcGFnZT0xJnBfc2VhcmNoX3RleHQ9cHJlLWVtcHRpb24gYW5kIG1hcmtldGluZw**&p_li=&p_topview=1.
[52] 42 C.F.R. §423.504(b)(4)(vi)(H). 42 U.S.C. §1395w-104. CMS provides guidance to plan sponsors in Chapter 9 of the Prescription Drug Benefit Manual, CMS, Chapter 9, *supra* note 11. CMS decided not to require mandatory self-reporting of misconduct. In response to public comments on the proposed rules, CMS eliminated the requirement it had initially proposed that Part D plan sponsors report to CMS "violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. 70 Fed. Reg., at 4334.

[53] 42 C.F.R. §423.504(b)(4)(vi)(E); CMS, Chapter 9, *supra* note 11, at 50.2.5.
[54] *Id.* 50.2.4.2.
[55] *Id.* 50.2.6,1,1.
[56] *Id.* 50.2.6.2.
[57] *Id.* 50.2.6.3.
[58] CMS, "Oversight Strategy," *supra* note 50. In an October 7 News Release, CMS described three methods of fighting fraud: using new techniques to fight fraud and abuse; working with "law enforcement, prescription drug plans, consumer groups and other key partners to protect consumers and enforce Medicare's rules;" and proving tips for consumers "so they can protect themselves." CMS, "Medicare Expands Efforts to Fight Fraud; New Work With Law Enforcement; More Consumer Awareness Planned As Prescription Drug Coverage Enrollment Nears" (Oct. 7, 2005), http://www.bcbs.com/medicare/pdf/final_protecting_part_D_release_2.pdf.
[59] CMS, Medicare Part D Reporting Requirements (updated 01/25/06), http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/PartDReportingRequirements_CurrentYear.pdf. Reporting requirements for contract year 2007 (updated 04/14/06) are at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/PartDReportingRequirements_NextYear.pdf.
[60] *Id.* 2.
[61] CMS, "Oversight Strategy," *supra* note 50, at page 6.
[62] *Id.*
[63] *Id.*
[64] 42 U.S.C. §1395w-112; 42 C.F.R. §423.504(d). *See also* CMS, Chapter 9, *supra* note 11.
[65] CMS, "Oversight Strategy," *supra* note 50, at page 3.
[66] 42 C.F.R. §423.505(e)(2); CMS, Chapter 9, *supra* note 11, at 50.2.6.4.
[67] CMS, "Oversight Strategy," *supra* note 50, at page 3.
[68] *Id.*
[69] *Id.* page 2.
[70] 42 C.F.R. §423.156.
[71] Gary Bailey, Deputy Director, Center for Beneficiary Choices, "Complaints Tracking Improvement" (Mar. 29, 2006). The link to the memorandum, http://www.cms.hhs.gov/PrescriptionDrugCovContra/HPMSGH/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=2&sortOrder=descending&itemID=CMS063166, is inaccessible. When the report is clicked on, the message comes up, "You are not authorized to view this page." However, the Center for Medicare Advocacy requested and received a copy of the memorandum from CMS on May 18, 2006.
[72] CMS, "Oversight Strategy," *supra* note 50.
[73] Frequently Asked Question ID 6453 (Mar. 15, 2006), http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=6453&p_created=1134659003&p_sid=unHjG*ai&p_accessibility=0&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MyZwX3Byb2RzPTAmcF9jYXRzPSZwX3B2PSZwX2N2PSZwX3NlYXJjaF90eXBlPWFuc3dlcnMuc2VhcmNoX25sJnBfcGFnZT0xJnBfc2VhcmNoX3RleHQ9YmVuZWZpY2lhcnkgY29tcGxxhaW50cw**&p_li=&p_topview=1.
[74] *Id. See also* CMS, Chapter 9, *supra* note 11, at 50.2.6.4, note 75.
[75] Letter to CMS Administrator McClellan from Senators Grassley and Baucus (Apr. 13, 2006), http://finance.senate.gov/press/Gpress/2005/prg041306.pdf.
[76] "Part D Drug Benefit; Remaining Part D MEDIC Contracts To Be Awarded by End of September," *BNA Medicare Report*, Vol. 17, No. 34, page 1069 (Aug. 25, 2006).
[77] Mark McClellan, M.D., Ph.D., Administrator, "CMS' Expectations of Part D Sponsors" (Memorandum to All Part D Sponsors, Mar. 10, 2006), http://www.medicarerxguide.com/MDRG/2006/CMSExpectations_03.10.06.pdf.
[78] Letter from Mark B. McClellan, M.D., Ph.D., to The Honorable Pete Stark (May 3, 2006), http://www.house.gov/stark/news/109th/letters/20060517_CMS_Humana.pdf.
[79] Robert Pear, "Troubles Linger in Regulation of Medicare Customer Service," *The New York Times* (June 25, 2006), http://www.nytimes.com/2006/06/25/us/25medicare.html.
[80] CMS, "Medicare Details Steps Taken to Improve Customer Service by Drug Plans; Data Shows Improvements in Plan Call Center Wait Times," (News Release, June 29, 2006), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1890.
[81] 42 C.F.R. §423.507(b)(2)(i).
[82] *Id.* §423.507(b)(2)(ii), (iii).

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