November 26, 2003

Prescription Drug Benefit Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

EXECUTIVE SUMMARY

Congress has accepted the conference version of H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Act"), which is expected to be signed into law by the President. Following this Executive Summary is a memorandum that gives a top-level summary of the prescription drug benefit and related provisions of Title I of the Act.

Prescription Drug Coverage. Title I of the Act amends the Social Security Act to provide outpatient prescription drug coverage for Medicare beneficiaries beginning January 1, 2006. Coverage may be provided either through a prescription drug plan ("PDP") providing only drug benefits or through a Medicare Advantage plan that provides prescription drug coverage in addition to other health and medical benefits ("MA-PD plan"). Basic prescription drug coverage will cover prescription drugs and biologics covered by Medicaid, insulin and associated supplies, and all vaccines licensed by the Food and Drug Administration. Basic coverage also will allow enrollees access to the discounted prices that plans have negotiated with manufacturers, pharmacies, or other third parties. Plans also may offer supplemental coverage.

The Secretary will negotiate and approve bids from potential plan sponsors. Plan sponsors will bear some financial risk, but the government will share in this risk. In particular circumstances, the Secretary also may approve limited risk plans.

Employer Sponsored Plans. The Act provides that for every individual covered by a qualified retiree prescription drug plan who is eligible to enroll in a PDP or MA-PD plan but does not do so, the Secretary will pay a subsidy to the sponsor of the retiree drug plan.

Drug Discount Cards. Under the Act, Medicare beneficiaries may obtain drug discount cards providing access to negotiated prices on drugs from private entities within six months after the Act's passage. Drug discount cards are not subject to formulary or coverage requirements. Sponsors may charge only an annual enrollment fee of no more than $30 and a fee for the dispensed drugs. Low-income, discount card-eligible individuals also may receive transitional assistance in the form of government subsidies for the cost of covered drugs.

Electronic Prescribing. The Act does not require that prescriptions be transmitted electronically, but requires that standards be created and that programs for electronic transmission of prescriptions possess particular capabilities. The Act encourages the use of electronic prescribing by allowing additional payments to prescribers using a qualified system and by providing for the creation of a safe harbor from the criminal anti-kickback and physician self-referral laws for the provision of particular equipment and services.

Demonstration Projects. The Act extends the Secretary's existing authority to conduct demonstration projects to the new prescription drug benefit provisions. The Conference committee recommends several specific demonstration projects, and Title VI of the Act mandates a demonstration project that examines the issues surrounding the potential future transfer of drug coverage currently provided under Medicare Part B to the new part D.

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Just prior to its Thanksgiving recess, Congress voted to accept the conference version of H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Act"), which is expected to be signed into law by the President.[1] Title I of the new Act creates a prescription drug benefit plan for Medicare beneficiaries, as well as drug discount cards and transitional assistance for the period before full prescription drug benefits are available. It also provides subsidies to encourage employers to retain prescription drug coverage for retirees, includes provisions encouraging the use of electronic prescribing, and allows the Secretary of Health and Human Services ("Secretary") to conduct demonstration projects that will provide information for the future expansion or revision of the prescription drug benefit. This memo presents a top-level summary of the new prescription drug benefit and related provisions.

I. Prescription Drug Benefit Plans

At the present time, Medicare does not cover outpatient drugs except for those that cannot be self-administered or that have been specifically authorized for coverage.[2] The Act creates a new Part D of Title XVIII of the Social Security Act, which will provide for optional outpatient prescription drug coverage for Medicare beneficiaries beginning January 1, 2006.

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[1] All citations to the Act will be to the text of the bill as reported in the House Conference Report. All new statutory provisions created by this Title will be incorporated into the Social Security Act ("SSA"), codified at 42 U.S.C. § 301 *et. seq*.

[2] Currently covered drugs include immunosuppressive drugs following a Medicare-covered organ transplant, erythropoietin for persons with chronic renal failure who are on dialysis, some cancer chemotherapy drugs, and hemophilia clotting factors.

Elements of Coverage

The Act allows Medicare beneficiaries to obtain prescription drug coverage through a prescription drug plan ("PDP") that offers no other health or medical coverage or benefits or through a Medicare Advantage ("MA") plan[3] that provides prescription drug coverage in addition to health and medical benefits ("MA-PD plan"). For ease of reference, PDPs and MA-PD plans will be referred to collectively as "plans" throughout this memo.

Basic Coverage. Beneficiaries may purchase one of two types of "qualified prescription drug coverage" under the Act: "standard coverage," or "alternative coverage" with benefits actuarially equivalent to standard coverage.[4] All plans must provide access to negotiated prices.

For 2006, the annual deductible for standard coverage is $250, the initial coverage limit for payment purposes, including the annual deductible, is $2,250, and the annual threshold for "stop loss" or "catastrophic" coverage is $3,600 in expenditures by the beneficiary.[5] For costs above the deductible and below the initial coverage limit, the beneficiary must pay 25% coinsurance.[6] After the initial coverage limit is reached, the beneficiary must bear all costs until reaching the annual catastrophic threshold. Once the beneficiary exceeds that threshold, the

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[3] Medicare Advantage is the successor to the Medicare+Choice program, which offers a managed care option to Medicare beneficiaries. Title II of the new legislation transforms Medicare+Choice into Medicare Advantage. *See* H.R. 1 § 201 *et. seq*., reported in House Conf. Report 108-391 (Nov. 21, 2003).

[4] H.R. 1 § 101(a)(2), inserting Social Security Act § 1860D-2(a)(1).

[5] *Id.*, inserting § 1860D-2(b). All threshold amounts will increase annually by the annual percentage increase in average per capita aggregate expenditures for covered drugs by covered individuals. *Id.*

[6] *Id.*, inserting § 1860D-2(b)(2)(A). The sponsor may apply tiered copayments that are actuarially equivalent to a copayment of 25%.

individual will not be required to pay more than 5% coinsurance or a copayment of $2 for generic drugs and preferred, multisource drugs and $5 for all other drugs. The Act includes a formula for determining the monthly premium for PDP enrollees, which the House Ways and Means Committee estimates will average $35 in 2006 for standard coverage.[7]

Low-income beneficiaries with incomes below 150% of the federal poverty level will receive subsidies.[8] Those with incomes between 135% and 150% of the federal poverty level will have a deductible of $50, and need pay only 15% coinsurance for all expenditures above this amount, until reaching the annual catastrophic threshold.[9] Those with incomes below 135% of the federal poverty level may not be charged more than $2 for generic drugs and preferred, multisource drugs and $5 for all other drugs, regardless of their level of drug utilization.

Individuals who are eligible for both Medicare and full Medicaid benefits ("Dual-Eligibles") whose income does not exceed 100% of the poverty line must pay $1 for each generic drug or preferred, multiple-source drug and $3 for any other drug.[10] Medicare is the primary payor for covered drugs for Dual-Eligibles, so Medicaid coverage is not available for these drugs or for any costs resulting from the cost-sharing provisions.[11] However, states may arrange to have PDPs and MA-PD plans provide coverage of non-covered drugs for all Medicaid beneficiaries, including Dual-Eligibles.

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[7] *Id.*, inserting § 1860D-13(a); Committee on Ways and Means, Summary of Medicare Conference Agreement: Title I - Medicare Prescription Drug Benefit 1 (Nov. 21, 2003).

[8] H.R. 1 § 101(a)(2), inserting § 1860D-14(a).

[9] *Id.* Copayments will increase annually by the percentage increase in the consumer price index.

[10] *Id.*, inserting § 1860D-14(a)(1)(D).

[11] *Id.* § 103(c), inserting § 1935(d).

A plan sponsor may provide alternative coverage of a different design if the Secretary approves the plan and if the actuarial value of the total coverage is not less than that of standard coverage. The plan's deductible may not exceed the deductible for standard coverage, and the plan must provide the same protections for high out-of-pocket expenditures.[12] The coverage must be designed to pay the same percentage of costs up to the initial coverage limit.

Beneficiaries must receive the benefit of the sponsor's price negotiations with manufacturers and pharmacies, including all discounts, rebates, other price concessions, and direct or indirect subsidies and remuneration. Standard and alternative coverage plans must provide these negotiated prices even when the plan is not obligated to pay any benefit because of the application of a deductible, cost-sharing, or initial coverage limit.[13] The Secretary may not interfere with the negotiations between drug manufacturers, pharmacies, and PDP sponsors.[14] The sponsor must issue a card or other technology, which may also be used in connection with benefits provided under a State Pharmaceutical Assistance program ("SPAP"),[15] to assure access to these negotiated prices.[16] The Secretary will provide standards, which will be compatible with the administrative simplification standards issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and with standards for electronic prescribing issued

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[12] *Id.* § 101(a)(2), inserting § 1860D-2(c).

[13] *Id.*, inserting § 1860D-2(d)(1).

[14] *Id.,* inserting § 1860D-11(i). This provision does not apply to negotiations by MA-PD organizations.

[15] *Id.*, inserting § 1860D-23(c)(2). SPAPs are state programs that provide financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits to enrollees of all eligible plans, without discriminating between plans. *Id.*, inserting § 1860D-23(b).

[16] *Id.*, inserting § 1860D-4(b)(2).

under the Act, for the development of a nationally standardized format for the card or technology.

Supplemental Coverage.[17] Supplemental coverage may take the form of a reduction in the annual deductible or coinsurance percentage, an increase in the initial coverage limit, a combination of the two, or coverage of a product that is excluded under the Medicaid definition of covered drugs.

Covered Drugs. The Act requires that plans cover those prescription drugs and biologics covered by Medicaid, insulin and associated supplies, and all vaccines licensed by the Food and Drug Administration.[18] A covered drug is covered for any medically accepted indication. The Act does not provide coverage for drugs excluded or restricted under Medicaid drug coverage, except those for smoking cessation. Drugs that are eligible for coverage under Medicare Part A or B will not be covered under the new Part D.[19] Plans may refuse to cover a drug that is not medically necessary or is not prescribed in accordance with the plan, but beneficiaries may appeal these exclusions.[20]

The Secretary may not require a particular formulary or institute any reimbursement price structure.[21] Any formulary adopted by a plan must be developed and

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[17] See Section IV for additional discussion related to alternative coverage.

[18] *Id.*, inserting § 1860D-2(e)(1).

[19] The Secretary must make recommendations to Congress by January 1, 2005, on the transitioning of drugs that are currently covered by Part B to coverage under these new provisions. *Id.* § 101(c).

[20] *Id.* § 101(a)(2), inserting § 1860D-2(e). PDP sponsors are subject to the requirements imposed on MAs for appeals procedures in SSA § 1852(g). *Id.*, inserting § 1860D-4(h).

[21] *Id.*, inserting § 1860D-11(i).

reviewed by a pharmacy and therapeutic committee meeting certain membership and procedural requirements, and it must include at least one drug within each therapeutic category and class.[22]

At the time of dispensing, the pharmacy must inform the beneficiary of any difference in cost to the beneficiary between the provided drug and the lowest-priced generic drug that is therapeutically equivalent, bioequivalent, and available from that pharmacy.[23]

Enrollee Eligibility

Medicare beneficiaries enrolled in MA-PDs may not enroll in a PDP. Beneficiaries are eligible to enroll in a PDP if they are enrolled in either a fee-for-service plan, a MA private fee-for-service plan that does not provide drug benefits, or a Medical Savings Account ("MSA") plan.[24] Dual-Eligibles will be enrolled automatically.[25] Individuals who enroll in a MA-PD plan will be limited in their ability to disenroll from that plan.[26]

Plan Requirements

Acceptance of Risk and Incentives. Plan sponsors must accept at least some financial risk. However, the Act creates risk corridors based on the amount actually paid by the sponsor under the plan.[27] The risk corridors limit both a plan's upside and downside risk. If plan spending exceeds the target amount by a set percentage, federal government payments to the plan will be increased, while payments will be reduced if spending is below the threshold. The

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[22] *Id.*, inserting § 1860D-4(b)(3).

[23] *Id.*, inserting § 1860D-4(k).

[24] *Id.*, inserting § 1860D-1(a)(1). These provisions do not address the eligibility requirements for MA-PDs, which are addressed elsewhere in the SSA, as amended by this Act.

[25] *Id.*, inserting § 1860D-1(b)(1)(C).

[26] *Id.* § 102(a)(6), inserting § 1851(e)(2)(C)(iii).

[27] *Id.* § 101(a)(2), inserting § 1860D-15(e).

Act establishes two risk corridors. The federal government takes on a greater portion of the risk in the second corridor, i.e., where the deviation from the target is greater. The risk corridors do not apply to fallback plans (described below) or to supplemental coverage.[28]

PDP sponsors may create "limited risk" plans, in which the risk is modified either by increasing the federal participation in the risk in the first or second risk corridor or by decreasing the size of the risk corridors.[29] The risk modification may not be so substantial that the plan has no risk or a *de minimis* level of risk.[30] Such a modification of risks will apply to all PDPs offered by that sponsor in that region.

The Act also provides subsidies to all sponsors of PDPs and MA-PDs other than fallback plans. These sponsors will receive subsidies, either through direct payments or through reinsurance, to reduce premiums for all beneficiaries consistent with an overall subsidy level of 74.5% for basic coverage.[31]

Plan Approval. In order to implement a PDP or MA-PD plan, the sponsor must submit a bid to the Secretary.[32] The Secretary may negotiate the bid and its terms and conditions and may approve the plan if it meets all statutory requirements, including the requirement that its design not "substantially discourage enrollment."[33] The same deadline will apply for bids for full risk and limited risk plans.

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[28] *Id.*, inserting §§ 1860D-15(e)(1)(B), (g).

[29] *Id.*, inserting § 1860D-11(b)(2)(E). This provision specifically states that it does not apply to MA-PD plans.

[30] *Id.*, inserting § 1860D-11(f).

[31] *Id.*, inserting §§ 1860D-15(a), (g).

[32] *Id.*, inserting § 1860D-11(b)(2).

[33] *Id.*, inserting §§ 1860D-11(d), (e).

While the Secretary may approve an unlimited number of full risk plans, he may approve only the minimum number of limited risk plans necessary to ensure that each beneficiary will be able to choose from at least two plans from two different sponsors.[34] If these access requirements are not met through use of full risk and limited risk plans, the Secretary will establish a separate process for the submission of bids for fallback plans.[35] Fallback plan bids may be submitted only by entities that did not submit a full risk or limited risk plan for any PDP region. A fallback plan may not offer either alternative or supplemental coverage, but may offer only standard prescription drug coverage, for which the Secretary will set the monthly beneficiary premium. In addition, the fallback plan may not market or brand its services and must meet particular performance measures in order to receive its contracted management fees.

Requirements for Approved Plans. The Secretary will establish PDP regions, which will be the same as MA regions to the extent practicable.[36] The service area for each PDP must consist of at least one PDP region, and the Secretary will create paperwork reduction incentives for plans covering more than one region.[37]

A plan must accept any pharmacy that meets the plan's terms and conditions, but may not accept pharmacies that provide service only by mail-order.[38] It also must allow enrollees to use non-network pharmacies, although it may require an enrollee to pay any

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[34] *Id.*, inserting §§ 1860D-3(a)(1), 1860D-11(f).

[35] *Id.*, inserting § 1860D-11(g).

[36] *Id.*, inserting § 1860D-11(a). MA regions will be established by the Secretary by January 1, 2005, under the new provisions of Title II of the Act, Regions will be designed to maximize the availability of MA regional plans, based on a market survey and analysis. There will be at least 10, and no more than 50, MA regions. *Id.* § 221(c), inserting § 1858(a)(1).

[37] *Id.* § 101(a)(2), inserting § 1860D-11(b)(3).

[38] *Id.*, inserting § 1860D-4(b)

differential in charges. The plan cannot require pharmacies to accept insurance risk as a condition of enrollment.

The Act requires a sponsor to establish a drug utilization management program that includes incentives to reduce costs when medically appropriate, as well as a program to control fraud, abuse, and waste. The sponsor also must implement quality assurance measures to reduce medication errors and adverse drug interactions and to improve medication use.[39] Furthermore, the sponsor must create a medication therapy management program for targeted beneficiaries, who are those with multiple chronic diseases, who are taking multiple covered drugs, and who are likely to incur annual costs for covered drugs exceeding an amount specified by the Secretary.[40] The program may include compliance programs to enhance enrollee understanding of the appropriate use of medications and reduce the risk of adverse events, as well as elements to detect adverse events and patterns of drug overuse and underuse. The sponsor may factor into its fees the cost of implementing this program.

The Act imposes requirements for procedures for grievances, exceptions to the tiered cost-sharing structure, coverage determinations and reconsiderations, and appeals.[41] Beneficiaries may appeal a plan's decision to refuse a formulary exception or to refuse to cover a non-formulary drug only if the prescriber determines that all drugs on any tier of the formulary would be less effective for the individual, would cause adverse effects, or both.[42]

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[39] *Id.*, inserting § 1860D-4(c).

[40] *Id.* Note that while the language of the legislation provides that a targeted beneficiary is one who meets all three criteria, the Conference Agreement reads this provision to require only one of these three criteria to apply. House Conf. Report 108-391 at 454 (Nov. 21, 2003).

[41] H.R. 1 § 101(a)(2), inserting §§ 1860D-4(f), (g)(1), (h)(1).

[42] *Id.*, inserting §§ 1860D-4(g)(2), (h)(2).

Sponsors of PDPs and MA-PDs must meet requirements that will be established by the Secretary regarding coordination with SPAPs, Medicaid, group health plans, federal employees health benefits plans, military coverage, and other health benefit plans providing prescription drug coverage.[43]

Particular Programs. Beginning January 1, 2006, MA organizations may offer a MA coordinated care plan only if the organization provides at least one MA-PD plan in the service area.[44] Organizations may not offer prescription drug coverage under a MSA plan. Special rules apply to reasonable cost reimbursement contracts, PACE plans, and private MA fee-for-service plans.[45]

Medigap issuers cannot be required by the state or federal government to sponsor PDPs.[46] Individuals enrolling in a PDP or MA-PD plan may not also enroll in or renew a private insurance Medigap plan providing prescription drug coverage.[47] Medigap issuers may renew existing policies containing prescription drug coverage for enrollees who are not also enrolled in a PDP or MA-PD plan, but may not sell or issue any plan providing prescription drug coverage to new enrollees. Individuals are guaranteed enrollment in particular types of Medigap plans if they were enrolled in a Medigap policy that included drug coverage and terminated that enrollment to enroll in a PDP or MA-PD plan during the initial Part D enrollment period. The

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[43] *Id.*, inserting §§ 1860D-11(j), 1860D-23(a), 1860D-24(a).

[44] *Id.*, inserting § 1860D-21(a)(1).

[45] *Id.*, inserting §§ 1860D-22(d)-(f).

[46] *Id.* § 104(c).

[47] *Id.* § 104(a)(1), inserting § 1882(v).

Act also provides for the revision of standard Medigap benefits packages, including the creation of two new benefit packages.[48]

Employer Sponsored Programs

For every individual covered by a qualified retiree prescription drug plan who is eligible to enroll in a PDP or MA-PD plan but does not do so, the Secretary will pay a subsidy to the sponsor of the retiree drug plan.[49] Each year, the Secretary will pay the sponsor a subsidy equaling 28% of the costs incurred under the plan that exceed $250 but are below $5,000, whether those costs were paid by the plan or by the retiree.

The Act defines "qualified retiree prescription drug plans" as employment-based group health plans, including ERISA welfare plans, federal and state government plans, collectively bargained plans, and church plans, that provide prescription drug coverage of an actuarial value at least equal to that of standard coverage offered under the Act.[50] These plans need not meet any other requirements imposed on PDPs and PD-MA plans.[51]

Information Exchange

The Secretary can provide relevant information about Medicare-eligible individuals to PDP sponsors and MA-PD organizations, which these entities may use only for marketing and enrollment purposes.[52] The Secretary must provide comparative information

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[48] *Id.* § 104(b), inserting § 1882(w).

[49] *Id.* § 101(b)(2), inserting § 1860D-22(a).

[50] *Id.*, inserting § 1860D-22(c)(3).

[51] *Id.*, inserting § 1860D-22(a).

[52] *Id.*, inserting § 1860D-1(b)(4).

about plan benefits to current and prospective beneficiaries.[53] The Act also specifies the timing and content of information that plans must provide to enrollees, including specific rules for the explanation of benefits, initial coverage limit and out-of-pocket threshold, and formulary changes.[54]

II. Drug Discount Cards and Transitional Assistance

The Act makes drug discount cards and transitional assistance available until the full prescription drug benefits begin on January 1, 2006. Discount cards and transitional assistance are to be available no later than six months after enactment of the Act.[55] Enrollment in a discount card program is voluntary, and eligible individuals may enroll in no more than one program.[56] Sponsors may charge enrollees only an annual enrollment fee, which must be uniform throughout a state and not exceed $30, and a fee for the dispensed drugs. Sponsors and pharmacies may charge no other fees related to these programs.[57]

Discount card holders will be entitled to negotiated prices on drugs, which must reflect all discounts, rebates, and direct or indirect subsidies and remuneration received by the program sponsor, and will include any dispensing fees for the drugs.[58] Individuals eligible for transitional assistance (described below) also will receive government subsidies for up to 90%

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[53] *Id.*, inserting §§ 1860D-1(c)(3)(A), 1860D-4(d).

[54] *Id.*, inserting § 1860D-4(a).

[55] *Id.*, inserting § 1860D-31(a)(2).

[56] *Id.*, inserting §§ 1860D-31(a)(3), (c)(1)(C).

[57] *Id.*, inserting §§ 1860D-31(e)(1)(C), (c)(2).

[58] *Id.*, inserting § 1860D-31(e)(1)(A).

(95% in the case of individuals eligible for special transitional assistance) of the costs of covered drugs, up to $600.[59]

Any person entitled to benefits or enrolled under Medicare Part A, or enrolled in Medicare part B, is eligible for a drug discount card.[60] Individuals who are entitled to assistance for outpatient prescription drugs under Medicaid are not eligible. Transitional assistance is available to low-income, discount card-eligible individuals, unless they have existing drug coverage or assistance, and special transitional assistance is available to individuals with incomes below 100% of the federal poverty level who are eligible for transitional assistance.[61]

Sponsor and Program Requirements

Entities that may offer discount cards include pharmaceutical benefit management companies, wholesale or retail pharmacy delivery systems, insurers, and organizations offering Medicare Part C plans.[62] MA organizations and organizations offering enrollment under a reasonable cost contract may be subject to less stringent requirements than other entities. Potential drug discount card program sponsors must apply to the Secretary. The Secretary may limit the number of program contracts awarded in a state, although he must award at least two per state. The Secretary's decision not to endorse or enter into a contract with a program is not judicially reviewable.[63]

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[59] *Id.*, inserting §§ 1860D-31(g)(1)(B), (2)(A).

[60] *Id.*, inserting § 1860D-31(b)(1).

[61] *Id.*, inserting §§ 1860D-31(b), (f)(2).

[62] *Id.*, inserting § 1860D-31(h).

[63] *Id.* § 102(a)(2), inserting § 1860D-31(h)(2)(D); 105(c)(4).

A discount card program sponsor is not required to cover any particular class of drugs and need not meet any standards in the creation of formularies. Accordingly, sponsors apparently may provide benefits for only those drugs that they choose. However, sponsors may provide or market only those services that are directly related to a covered discount card drug or a discount price for a nonprescription drug.[64]

Programs must enroll sufficient pharmacies to ensure convenient access by enrollees.[65] The Secretary and the plan sponsor must make relevant information available to discount card-eligible individuals and enrollees.[66]

Sponsors of drug discount cards are "covered entities" for the purposes of the regulations issued under HIPAA, but the Secretary may waive the relevant privacy portions of those regulations for an "appropriate, limited period of time."[67]

III. Electronic Prescribing

The Act requires the Secretary to establish standards for electronically transmitted prescriptions.[68] The standards are to be compatible with the standards for the prescription drug plan cards issued under this Act, HIPAA administrative simplification standards, and general health information technology standards. Proposed standards must be in place by September 1, 2005, and final standards must be issued by April 1, 2008.

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[64] *Id.* § 102(a)(2), inserting § 1860D-31(h)(7).

[65] *Id.*, inserting § 1860D-31(e)(1)(B).

[66] *Id.*, inserting § 1860D-31(d).

[67] *Id.*, inserting § 1860D-31(h)(6).

[68] *Id.*, inserting § 1860D-4(e).

Electronic prescribing programs must provide the prescriber or pharmacist with information regarding the beneficiary's eligibility and benefits, possible drug interactions involving the prescribed drug, and any lower-cost, therapeutically appropriate alternatives to the prescribed drug on an interactive, real-time basis, to the extent practicable.[69] By some unspecified future date, the programs must be able to transmit the individual's relevant medical history, upon request.

The Act does not require that prescriptions be transmitted electronically, but allows a MA-PD plan to provide separate or differential payments to prescribers who use a system meeting these requirements.[70] The payment may be based on the prescriber's implementation costs, increases in formulary compliance, increased use of lower cost therapeutically equivalent alternatives, reductions in adverse drug interactions, and increased efficiency in filling prescriptions resulting from use of the system. The Secretary also will create a safe harbor from the criminal anti-kickback and physician self-referral laws to allow hospitals, group practices, and plan sponsors to give prescribers hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information.[71]

IV. Demonstration Projects

The Act specifies that the Secretary's existing authority to conduct demonstration projects extends not only to Medicare Parts A and B, but also to Part C and the new prescription

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[69] *Id.*, inserting § 1860D-4(e)(2).

[70] *Id.* § 102(b), inserting § 1852(j)(7).

[71] *Id.* § 101(a)(2), inserting § 1860D-4(e)(6).

drug benefit under Part D.[72] Under this demonstration authority, the Secretary may waive reimbursement and coverage requirements in order to conduct demonstrations.[73] The Conference committee notes that, under the present system, reinsurance provides the private sector with disincentives to offering supplemental prescription drug benefits. The Conference report states that the Conference committee intends the Secretary to use this demonstration authority to allow private sector plans the maximum flexibility in designing alternative drug coverage so that the Secretary may evaluate new methods for providing reinsurance that remove these disincentives. The committee suggests several areas worthy of exploration through demonstration.

Specifically, the Conference committee suggests that the Centers for Medicare and Medicaid Services ("CMS") institute a demonstration project that assesses the impact of covering through capitated payments the existing gap in services between the initial coverage limit and the annual threshold.[74] Under this project, CMS would make capitated payments that are actuarially equivalent to the reinsurance that the government would otherwise provide when the beneficiary reaches the catastrophic level.

The Conference committee also suggests that CMS demonstrate the impact of providing flexible benefits by altering reinsurance payments for MA plans, regional preferred provider organizations ("PPOs"), or PDPs that participate in a waiver program, and then

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[72] *Id.,* inserting § 1860D-42(b).

[73] House Conf. Report 108-391 at 440 (Nov. 21, 2003).

[74] *Id.* at 440-441.

comparing these plans' spending with that of plans continuing to receive funding according to the terms of Title I.[75]

Finally, the committee suggests that CMS use the demonstration authority to determine whether paying MA plans or regional PPOs to provide non-Medicare benefits would increase efficiency in the provision and utilization of health care services.[76] Specifically, these entities would be paid to provide prescription drug coverage or preventive services not currently covered under any provision of Medicare, although CMS's activities must remain budget neutral.

In Title VI, the Act mandates that CMS create a demonstration project providing for cost-sharing of prescription drugs and biologicals that currently are covered under Medicare Part B in the same manner that cost-sharing will apply to outpatient pharmaceuticals under the Act.[77] The project specifically will involve self-administered oral anticancer chemotherapeutic agents, as well as drugs and biologicals furnished incident to a physician's professional service. The project, which will begin 90 days after enactment of the Act and end by December 31, 2005, is limited to 50,000 patients and may receive up to $500 million in funding. The Secretary will report to Congress by July 1, 2006, on patient access to care, patient outcomes, and cost effectiveness under the program.

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[75] *Id.* at 441.

[76] *Id.*

[77] H.R. 1 § 641.

We are continuing to analyze the implications of this sweeping new legislation and will be following closely as CMS issues regulations and takes other actions necessary to implement the prescription drug benefit and related provisions. If you would like further information about the implications of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or other aspects of the Medicare provisions of the Social Security Act please contact:

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