The Low-Income Subsidy in the New Medicare Drug Benefit

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I. The Medicare Prescription Drug, Improvement, and Modernization Act

On December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act into law. The legislation was enacted primarily because the traditional Medicare program – first enacted in 1965 – did not reflect the state of modern medicine in 2003, most notably because of the absence of Medicare coverage for the vast majority of outpatient prescription medications. In enacting the law, Congress and President Bush both expressed special concern about the inability of senior citizens to afford prescription medications as a primary reason in enacting the

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2 See H.R. Rep. No. 108-391 at 427 (2003) (noting addition of a prescription drug benefit to Medicare as “a critical modernization of the program”) [hereinafter MMA Conf. Rep.]. See also 39 WEEKLY COMP. PRES. DOC. 50 at 1771 – 74 (Dec. 15, 2003) (quoting President Bush’s description of the necessity of the legislation) [hereinafter Signing Statement]. Congress focused more on the need for prescription drug coverage under the Medicare program, and the needs of seniors. See MMA Conf. Rep. at 427 (noting that the typical senior citizen takes over 20 prescriptions per year, while 25% of seniors have no coverage for those drugs). President Bush, while focusing on the importance of a drug benefit, also stressed the need for modernization of the program. See Signing Statement at 1773 (noting that the legislation achieves a “second great goal” of providing more options for Medicare beneficiaries to receive their health care).
MMA.\(^3\) After enactment of the drug benefit, President Bush estimated that Medicare beneficiaries who elected the benefit would see their drug costs reduced by fully one-half after paying a premium of $35 per month.\(^4\)

Medicare beneficiaries with limited incomes would be unlikely to elect to obtain the drug benefit if they were unable to afford the premium and cost sharing under the MMA – the remaining “one-half” of drug costs to which the President referred. As a result, the MMA provides subsidies to lower income Medicare beneficiaries.\(^5\) The availability of these subsidies raises significant legal issues that go to the heart of the traditional Medicare and Medicaid programs.

This article analyzes those issues. It begins with a discussion of current drug coverage that is available in the traditional Medicare program.\(^6\) It then describes the structure of the MMA and explains the applicable cost-sharing requirements.\(^7\) After that discussion, the article describes the low-income subsidy.\(^8\) It then discusses the means by which individuals may claim the subsidy.\(^9\) It concludes by applying the legal analysis that would apply to a claim for the subsidy,\(^10\) describing how the agencies enrolling Medicare beneficiaries in the subsidy view the issue of judicial review.

A. Drug coverage under the traditional Medicare Program

The MMA is a significant expansion of the Medicare program. Although the traditional Medicare program did not cover most outpatient prescription medications, prior to the MMA, coverage was available for five limited classes of medications. These statutory categories remain even after enactment of the MMA.

The first class is those drugs administered “incident to” a physician’s service, if

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\(^3\) See MMA Conf. Rep. supra note 2, at 427 (noting the “unacceptable choices” that low-income Medicare beneficiaries make between paying for medications and other necessities of life). See also Signing Statement, supra note 2, at 1772 (describing senior citizens who reduce dosages of medication “to make a bottle of pills last longer”).

\(^4\) See Signing Statement, supra note 2, at 1772 (noting that seniors without drug coverage would “see their current drug bills cut roughly in half”).


\(^6\) See infra text accompanying notes 11-26.

\(^7\) See infra text accompanying notes 27-49.

\(^8\) See infra text accompanying notes 50-73.

\(^9\) See infra text accompanying notes 74-180.

\(^10\) See infra text accompanying notes 181-198.
those drugs cannot usually be self-administered. The most common example is drugs used as chemotherapy treatment for cancer patients, as well as anti-emetic agents used to treat chemotherapy-induced nausea and vomiting, although newer pharmaceuticals – such as certain drugs used to treat rheumatoid arthritis and multiple sclerosis – are also covered under the "incident to" category. The second class of drugs covered under the traditional Medicare program are drugs used in immunosuppressive therapy following discharge from a hospital for a Medicare-covered organ transplant. Next, the traditional Medicare program covers blood clotting factors for hemophilia patients competent to use the factors without medical supervision. In addition, Medicare covers erythropoietin alfa for the treatment of anemia in patients with end-stage renal disease who are on dialysis. Finally, in addition to the not-usually-self-administered chemotherapy and anti-emetic agents, Medicare pays for some oral forms of those medications.

Medicare covers these drugs under Part B of the program. Part B is voluntary, in the sense that a Medicare beneficiary must elect to enroll in the program. It covers predominantly physician and other health professional services. Upon

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11 See 42 U.S.C. § 1395x(s)(2)(A) (2005) (creating a benefit category for such drugs). The Centers for Medicare & Medicaid Services, the agency that administers the Medicare and Medicaid programs, takes the position that a drug is not “usually” self-administered if, for more than 50% of patients, it must be administered by injection or intravenously. See CTRS. FOR MEDICARE & MEDICAID SERVS, TRANSMITTAL AB-02-072, CHANGE REQUEST 2200 (May 15, 2002) [hereinafter CMS Transmittal] (providing definition of “usually” in § 1395x(s)(2)(A)).

12 See CMS Transmittal, supra note 11, at 2.


16 See 42 U.S.C. § 1395x(s)(2)(Q) (2005) (creating benefit category for oral forms of chemotherapy medications), 42 U.S.C. § 1395x(s)(2)(T) (2005) (creating benefit category for oral forms of anti-emetic agents). Note that the standard for coverage of both is different; whereas oral forms of chemotherapy medications are covered if the oral forms of the medication contain the “same... active ingredient” as the IV-administered form of the medication, oral forms of anti-emetic agents are covered regardless of whether the oral form contains the “same” ingredient. To be covered as an oral anti-emetic agent, however, the drug must constitute “a full replacement” for the IV therapy that would have otherwise been given. See id. at § 1395x(s)(2)(T)(ii)(2005).


19 See 42 U.S.C. § 1395k(a)(2005) (listing scope of Part B benefits). To the extent that Medicare does provide coverage for outpatient prescription drugs, it is because they are treated as “medical and other health services” under 42 U.S.C. § 1395k(a)(2)(B), as that term is defined in 42 U.S.C. §
enrollment by a beneficiary, the beneficiary’s payment of a premium, and the satisfaction of an annual deductible, the program will generally pay 80% of the reasonable charges for the Part B service, with the beneficiary liable for the remainder. There is no catastrophic “cap” on beneficiary exposure under Part B; if Medicare authorizes a $100,000 payment for a particular Part B procedure, a beneficiary who has satisfied the annual Part B deductible is liable for the $20,000 remainder and must pay it out of pocket in the absence of other insurance.

Historically, the Medicare program paid for Part B drugs on the basis of 95% of the average wholesale price (AWP) of the drug. Congress, the Government Accountability Office, and the HHS Office of Inspector General have all noted the tremendous inefficiency of such a reimbursement methodology. As a result, as part of the MMA, Congress directed the Medicare program to replace the AWP system for Part B drugs with a system that does not rely on manufacturer’s reported charges, but rather, the average sales price of those drugs, as determined based on sales in the free market.

1395x(s). Institutional services under Medicare are authorized under Part A of the program. Although Medicare does pay for limited prescription drugs under Part A, a discussion of those drugs is beyond the scope of this article.

20 See 42 U.S.C. § 1395(a)(1) (2005) (authorizing payment of benefits equal to 80% of reasonable charges). Although the Medicare program, as first enacted in 1965, authorized payment of providers on the basis of charges, Congress eventually realized the inefficiency of such a system, and replaced it with other mechanisms. As will be evident shortly, one such mechanism was created as part of the MMA. See generally MMA § 303.

21 Unlike Part A services, many Part B services are not paid on an assignment-related basis. See generally 42 U.S.C. § 1395u(b)(6) (2005) (providing that the right to payment belongs only to the beneficiary who received the service unless made “pursuant to an assignment”, in which case payment can be made directly to the provider). As a result, if a beneficiary receives a Part B service from a provider who does not accept assignment, they may be liable for charges in excess of the 20% remainder. Congress has sometimes limited beneficiary exposure in such circumstances, however. See e.g., 42 U.S.C. § 1395w-4(g)(2005) (limiting beneficiary out-of-pocket costs for physicians who do not agree to accept assignment).


24 See MMA Conference Report, supra note 2, at 582-84 (2003) (noting “substantial evidence” that average wholesale price of Part B drugs dramatically exceeds the cost to physicians of obtaining those drugs). The AWP reimbursement methodology calls into serious question the wisdom of the idea, often expressed by some members of Congress and editorial pages in the mainstream media, that the federal government should somehow attempt to regulate prescription drug prices. In the one area where the federal government has, in fact, done so, the evidence is legion that the federal government and Medicare beneficiaries have dramatically overpaid for those drugs.
marketplace. Under the new provision, Medicare began reimbursing for Part B drugs at 106% of the average sales price of the drug on January 1, 2005.

B. MMA’s broader coverage of outpatient prescription drugs

As we have seen, coverage for outpatient prescription drugs under the traditional Medicare program was extremely limited, complicated, left beneficiaries exposed to large out-of-pocket expenditures, and was inefficient for taxpayers and beneficiaries. Congress was especially concerned about the large number of Medicare beneficiaries who had no access to outpatient prescription drugs that were not Part B drugs: commonly-prescribed drugs for the elderly such as medications to treat hypertension, hyperlipidemia, diabetes, and congestive heart failure. Because all of those drugs – and countless others – did not meet the definition of a Part B drug (all are self-administered and are not administered incident to a physician’s service), Medicare beneficiaries lacked access to them in the absence of supplemental insurance. Congress estimated that as many as 25% of beneficiaries fell into this category. The MMA was designed, in large part, to address their plight.

Under the MMA, Medicare coverage is available for a drug if it is a “covered Part D drug.” “Covered part D” drugs are, obviously, a broader class of drugs than Part B drugs. A drug is a part D drug if it meets two tests. First, it must be a drug or biological product that can only be dispensed upon a written prescription. Second, it must be approved by the FDA. In addition, certain classes of drugs, such as

26 See id. Beginning January 1, 2006, physicians can opt out of the system and have drugs furnished under a competitive acquisition program where physicians never take title to the drugs. See 42 U.S.C. § 1395w-3b (implementing competitive acquisition program).
27 See MMA Conference Report, supra note 2 at 427.
28 More specifically, each Medicare beneficiary “is entitled to obtain qualified prescription drug coverage.” 42 U.S.C. § 1395w-101(a)(1) (2005). “Qualified prescription drug coverage” includes “standard prescription drug coverage.” 42 U.S.C. § 1395w-102(a)(1)(A) (2005). “Standard prescription drug coverage” is defined to mean “coverage of covered Part D drugs.” Id. at subsection (b). As always under the Medicare program, the availability of a benefit category does not mean that a beneficiary can obtain the benefit; a Medicare benefit generally is only available if it is “reasonable and necessary” to treat the beneficiary’s medical condition. See 42 U.S.C. § 1395y(a)(1)(A) (2005) (providing that payment may not be made under the program for a benefit that is not “reasonable and necessary” for the patient’s medical condition). The “reasonable and necessary” standard applies for purposes of Part D. See 42 U.S.C. § 1395w-102(e)(3)(A) (2005) (authorizing application of the standard in Part D).
30 See id. (applying 42 U.S.C. § 1396r-8(k)(A)(i) to part D drugs).
prescription vitamins, are excluded from coverage as covered part D drugs.\textsuperscript{31} Importantly, covered part D drugs do not include drugs that are covered under parts A or B of the Medicare program; those drugs remain covered under the traditional Medicare program.\textsuperscript{32}

Unique to the MMA is the delivery of the prescription drug benefit. Under the traditional Medicare program (with limited exceptions in part C of the program), the federal government authorizes the benefit structure, sets the payment amounts, and defines the parameters of the scope of covered benefits, and administers the program through the Centers for Medicare & Medicaid Services (CMS). By contrast, under part D, the benefit will be delivered through private insurers who will design the benefit package (consistent with statutory parameters), determine payment amounts through direct negotiations with pharmaceutical manufacturers, and determine prescription drug formularies. The entities providing the benefit will receive a subsidy from the federal government for doing so.

There are only two ways for beneficiaries to receive the drug benefit if they elect to receive it.\textsuperscript{33} The first option is for beneficiaries enrolled in the traditional Medicare fee-for-service program to obtain the benefit through a Prescription Drug Plan, or PDP.\textsuperscript{34} The second option, available to beneficiaries enrolled in the part C Medicare Advantage program, is to receive the benefit through a Medicare Advantage Prescription Drug (MA-PD) plan;\textsuperscript{35} generally, these individuals must receive the benefit through their

\textsuperscript{32} See id. at subparagraph (B). Interestingly, there will likely be some drugs that will be part B drugs for some Medicare beneficiaries, but part D drugs for other beneficiaries. For example, some oral anti-emetic agents which serve as a “full replacement” for IV forms of anti-emetic therapy for some beneficiaries may not serve as a “full replacement” for IV forms of the therapy for other beneficiaries. As a result, those beneficiaries who qualify for coverage under the “full replacement” theory of clause (ii) of 42 U.S.C. § 1395x(s)(2)(T) will have the drug covered under part B, while those who do not qualify for coverage under that clause will have the drug covered under part D.

\textsuperscript{33} The program is voluntary, and as such, a beneficiary is free not to enroll. Those who do not enroll when they first become eligible for Medicare, however, are liable for a late enrollment penalty if they later enroll, unless they have creditable coverage. See 42 U.S.C. § 1395w-113(b)(2) (2000 & Supp. I. 2004). Individuals who do have creditable coverage – for example, as a retiree of a former employer – are free to continue obtaining drug coverage from that former employer. Employers that do offer drug benefits are eligible to receive a tax free subsidy payment. See 42 U.S.C. § 1395w-122(a)(1) (2000 & Supp. I. 2004) (authorizing subsidy) and I.R.C. § 139A (2005) (excluding value of subsidy from gross income).

This concept of providing the benefit directly through private insurers has as its genesis the Medicare managed care program that began in 1982 and later expanded in the Medicare+Choice (now, under the MMA, the Medicare Advantage) program. Beneficiaries are entitled not to the benefit as operated by the government, but rather, to the benefit structured by the PDP or MA-PD plan to which subsidies are provided by the government. In this sense, the program resembles more closely a defined contribution program (such as an employer's § 401(k) plan) rather than a defined benefit plan (such as a traditional pension that guarantees a particular dollar amount on retirement). With a defined contribution program, such as this, the entitlement is to the subsidy, not to the benefit.

Standard prescription drug coverage consists of the following elements. First, a beneficiary must pay a monthly premium. In 2006, when the benefit begins, that premium is expected to be approximately $35 per month. In exchange for the monthly premium, standard prescription drug coverage requires the beneficiary to pay a $250 deductible in 2006 before drug coverage becomes available. At that point, the PDP or MA-PD plan will provide 75% coverage of the covered part D drug, with the beneficiary liable for 25% coinsurance. Once the beneficiary has reached the "initial coverage limit," drug coverage under the plan stops; in 2006, the initial coverage limit is $2,250. However, to the extent that a beneficiary has, in 2006, incurred at least $3,600 in out-of-pocket prescription drug costs, they qualify for catastrophic coverage under the plan. Catastrophic coverage consists of beneficiary coinsurance equal to the

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36 Id. at § 1395w-101(a)(1)(B)(ii).
40 The premium amount is not specified in the statute; rather, the statute describes the formula that will be used to calculate the premium. See id. CMS has estimated the premium amount, however. See http://questions.medicare.gov/cgi-bin/medicare.cfg/php/enduser/std_alp.php (accessed April 10, 2005).
greater of 5% of the negotiated price of the drug or $2 (for a generic drug) or $5 (for a brand name drug); like most dollar amounts in the drug benefit, these are indexed for inflation after 2006.45

The provision of the law requiring a beneficiary to incur out-of-pocket costs before the catastrophic benefit becomes available requires that the beneficiary pay those costs generally on their own behalf. In particular, the out-of-pocket costs must be paid "by the part D eligible individual."46 Costs will be treated as paid by the individual if they are paid for "by another person (such as a family member) on behalf of the individual"; they cannot, however, be "reimbursed through insurance or otherwise."47 In addition, payments by a state pharmacy assistance program also count as true out-of-pocket spending.48 CMS takes the position that payments made by a charity count as payments by "another person" and therefore true out-of-pocket spending.49

II. The Low-Income Subsidies Under Part D

A. The available subsidies

The MMA makes available subsidies to lower-income Medicare beneficiaries who would otherwise likely be unable to afford the monthly premium, the deductible, cost-sharing, and the coverage gap without those subsidies. Under the statute, there are two classes of individuals eligible for the low-income subsidy. The first class is an individual whose income is less than 135% of the federal poverty level or who is a "full-benefit dual eligible."50 The second class is an individual not eligible under the first

47 Id.
48 Id.
50 See generally 42 U.S.C. §§ 1395w-114(a)(1) (2000 & Supp. I. 2004) (describing first class of eligible individuals) and 1395w-114(a)(3)(B)(v)(I) (2000 & Supp. I. 2004) (providing that full-benefit dual eligible individuals are treated as being in the first class of eligible individuals). The statute defines "full-benefit dual eligible individuals" as those individuals who have coverage for the month under a PDP or MA-PD plan and who are entitled to "full benefits" under Medicaid. 42 U.S.C. § 1396u-5(c)(6)(A) (2000 & Supp. I. 2004). The reference to “full benefit” refers to the so-called Medicaid "mandatory" populations – those individuals who states must cover under their Medicaid plans and who must receive the mandatory range of services under a state Medicaid plan. It does not include those individuals eligible for limited Medicaid benefits, such as Medicaid coverage only for Medicare Part A or B coinsurance and deductibles. See 70 Fed. Reg. 4194, 4369 (January 28, 2003) (to be codified at 42 C.F.R. pt. 423.773) [hereinafter the
class, but whose income is less than 150% of the federal poverty level. In addition, as will be described in the description of both classes, an asset test also applies to eligible individuals.

B. The first subsidy class: dual eligible individuals and those with income less than 135% of the federal poverty level

The most generous low-income subsidy is available to the lowest income, consisting of two classes of individuals. The first is those eligible for both Medicare and Medicaid. The second is for those with incomes less than 135% of the federal poverty level applicable to the relevant family size. In addition, individuals applying for the subsidy in this class may not have more than $6,000 in assets ($9,000 for a couple) in

MMA Title I regulation] (describing those Medicaid beneficiaries who would not be eligible for the subsidy). In addition, the Secretary has discretion to deem other individuals as full-benefit dual eligible if they are eligible for full benefits under the Medicaid program. See 42 U.S.C. § 1396u-5(c)(6)(A)(ii) (2000 & Supp. I. 2004).


Congress has, in the past, limited the ability of applicants for Medicaid to deed assets to others, such as to a family member or to a trust, in order to qualify for Medicaid long-term care benefits. 42 U.S.C. § 1396p (2000 & Supp. I. 2004). Very generally, if an individual transfers assets for less than fair market value and then seeks to apply for Medicaid for institutional services within a “look-back” period, the applicant must pay for a portion of those services herself. Id. at § 1396p(c)(1)(A). The look-back period is generally 36 months for transfers to natural persons, and 60 months for transfers to a trust. Id. at § 1396p(c)(1)(B). These rules do not apply for purposes of the Part D low-income subsidy. See MMA Title I regulation, supra note 50, at 4374 (noting that assets transferred for less than fair market value will not be deemed available to the transferor).

Once the drug benefit begins in 2006, Medicaid will generally no longer pay for prescription drugs for dual-eligible individuals. See 42 U.S.C. § 1396u-5(d)(1) (2000 & Supp. I. 2004) (providing that federal matching payments are not available for prescription drugs provided to dual-eligible individuals). State Medicaid plans may pay for drugs for this population that are excluded from the definition of part D drugs, however. Id. at subsection § 1396u-5(d)(2). Although the assumption of these costs relieves states of an enormous liability, it is not free; under the so-called “clawback” provision of the MMA, states must pay back to the federal government a portion of the savings it receives. See generally 42 U.S.C. § 1395u-5(c) (2000 & Supp. I. 2004) (enacting payback mechanism).

See 42 U.S.C. § 1395w-114(a)(1) (2000 & Supp. I. 2004) (describing income threshold “applicable to a family of the size involved”). CMS suggested that it had discretion to limit “family of the size involved” to the applicant and his or her spouse. See MMA Title I regulation (supra note 50) at 4368 (noting that CMS “considered” this approach). It rejected this interpretation, however. See id. As a result, applicants who live in large families (with, for example, dependent relatives) will be able to qualify for the subsidy even though they may not have qualified under the narrower interpretation. See id. at 4368-69. CMS thus interpreted the statute to permit a greater number of individuals to qualify for the subsidy.
In subsequent years, these levels are indexed for inflation. CMS generally follows the SSI definition of resources and feels that it lacks the statutory authority to deviate from that definition.

If an individual qualifies for the low-income subsidy as a member of this class, the individual receives significant financial assistance. First, the individual is not liable for the monthly premium. In addition, to the extent that the individual enrolls in part D late, 80% of the otherwise applicable late enrollment penalty is waived. Second, the individual is not liable for the otherwise applicable part D deductible. Third, the individual is eligible for coverage beyond the initial coverage limit.

In addition, individuals eligible for the subsidy have reduced cost sharing. The amount of the reduced cost sharing depends on whether the individual is institutionalized, very low-income, or otherwise. Institutionalized individuals in this eligibility class are liable for no cost-sharing. Eligible individuals who are not institutionalized and who have income up to 100% of the federal poverty level are liable for cost sharing equal to $1 for a generic drug, and $3 for a brand name drug. And eligible individuals with income between above 100% of the federal poverty level and below 133% of the federal poverty level are liable for cost sharing equal to $2 for a generic drug and $5 for a brand name drug. Finally, eligible individuals in this subsidy class are not subject to additional cost-sharing once they have reached the catastrophic attachment point.

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57 See MMA Title I regulation, supra note 50, at 4373-76.

58 42 U.S.C. § 1395w-114(a)(1)(A) (2000 & Supp. I. 2004). The premium waiver is limited to the amount of the “low-income benchmark premium” — generally, the lowest premium in a PDP region for basic part D coverage. Id. at § 1395w-114(a)(1)(B).

59 See id. at § 1395w-114(a)(1)(B).


C. The second subsidy class: individuals with income between 135-150% of the federal poverty level

A somewhat less generous subsidy is available to subsidy-eligible individuals who do not qualify for the subsidy available to lower-income beneficiaries: those with income at or above 135% of the federal poverty level, but less than 150% of the federal poverty level. Individuals qualify for this subsidy if they meet the income test and if they have assets less than $10,000 for an individual or $20,000 for a married couple. These amounts are also indexed for inflation. The identical rules that apply with regard to family size and assets also apply for purposes of this subsidy class.

If an individual qualifies for the subsidy as a member of this class, they are also eligible for significant financial assistance, albeit not as generous as the subsidy available to dual-eligible individuals and those with income under 135% of the federal poverty level. Individuals eligible in the second eligibility class must pay a premium on a sliding scale. These individuals also pay a deductible of $50 in 2006, indexed for inflation in subsequent years. These beneficiaries, like the beneficiaries eligible in the first eligibility class, retain prescription drug coverage beyond the initial coverage limit, although must pay cost sharing for that coverage. With regard to cost sharing, individuals in this eligibility class pay cost sharing up to and through the initial coverage limit of 15%. Finally, once the beneficiary has reached the catastrophic attachment point, their cost sharing is limited to $2 for a generic medication and $5 for a brand name medication.

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67 Id. at §1395w-114(a)(3)(E)(II).
68 See 42 C.F.R. § 423.773(b)(1) (applying family size policy for purposes of the entire regulation). See also MMA Title I regulation, supra note 50, at 4368 (explaining family size determination as applicable for purposes of the low-income subsidy generally) and 4374 (explaining asset test for purposes of general application of the low-income subsidy).
69 42 U.S.C. § 1395w-114(a)(2)(A) (2000 & Supp. I. 2004). The regulations describe the sliding scale in more detail. Specifically, an individual with income between 135% and 140% of the federal poverty level pays 25% of the premium. Individuals with income between 140% and 145% of the federal poverty level pay 50% of the premium. All other individuals in this subsidy class pay 75% of the premium.
III. Obtaining The Low-Income Subsidy

A. The application process

Individuals may apply for the subsidy in two places. The first option is that an applicant may apply for the subsidy at a state Medicaid office. The second is that the applicant may apply for the subsidy with the Social Security Administration. The issue of individuals applying for the subsidy through state Medicaid offices – and the difficulties that might arise if an applicant did so and states were then required to process their applications – prompted a fair number of comments to the title I regulation.

Some commentators believed that if an applicant applied at a state Medicaid office, that office should be able to merely accept the application and forward it on to the Social Security Administration for processing. Other commentators, representing states, said that allowing a dual application process would prove confusing and complicated to low-income applicants. These same observers noted that applicants will face “two competing processes” for the subsidy. Others noted the expense that states would incur in developing application systems, and the availability of limited federal matching funds for those expenditures. Finally, commentators noted that the application process for the low-income subsidy will not be the same as the application process for state Medicaid benefits, and therefore difficult for states to adapt to rapidly, beginning in 2006.

In response, CMS noted that the law gave the agency limited flexibility. The agency pointed to the requirement of the statute that determinations for eligibility be made by a state Medicaid agency “or” the Social Security Administration. And while appearing to sympathize with the commentators about the potential cost to states to make the low-income subsidy determinations, the complexity of the process, and the possibility of two different processes for obtaining the benefit, CMS could only point to

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75 See id. (allowing the eligibility determination to be made by the Commissioner of Social Security).
76 See Title I regulation, supra note 50, at 4381 (describing comments received).
77 Id.
78 Id. at 4381-82.
79 Id. at 4382.
80 See id. at 4381-82 (noting CMS response to comments).
the system

that Congress designed when drafting the statute.82 CMS also suggested several options for states to ease the burdens identified.83

The application process will be relatively straightforward for one class of beneficiaries, however. Individuals who are “full-benefit dual eligible” (i.e., entitled to both Medicare and Medicaid) are deemed to qualify for the most generous of the two classes of subsidies, described supra.84 Hence, these individuals – regardless of where they apply – will obtain the subsidy.

B. Administrative appeals of adverse decisions

An applicant who applies for the subsidy and whose application is denied has administrative appeal rights for reconsideration. Those appeal processes are available depending upon where the applicant applies for the subsidy. Applicants who apply through their state Medicaid agency go through the Medicaid appeals process.85 Applicants who apply with the Social Security Administration go through a redetermination process designed by the Commissioner.86 Appeals of adverse redetermination decisions are to be made consistently with the process that applies for purposes of denials of Supplemental Security Income (SSI) benefits or eligibility.87

82 See Title I regulation, supra note 50, at 4381-82 (noting that “the law is clear” and that eligibility determination process “based on statutory provisions”).
83 Id. at 4381 (suggesting that states use the Social Security application as the default application). CMS made other suggestions as well, including that states offer the SSA process to applicants. However, CMS notes that to the extent that an applicant insists that the state process their application for the subsidy, the statute requires that the state do so.
84 See 42 U.S.C. § 1395w-114(a)(3)(B)(v)(I) (mandating that the Secretary so treat full-benefit dual eligible individuals) and 42 U.S.C. § 1395w-114(a)(3)(B)(v)(II) (authorizing the Secretary to treat QMBs, SLMBs, and QIs as eligible for that subsidy class). A special note on these individuals is appropriate. Qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and qualifying individuals (QIs) are not entitled to the full range of Medicaid benefits under a state plan, but do qualify for Medicaid assistance in paying for some forms of Medicare cost sharing. The Secretary has elected to exercise this authority. See 42 C.F.R. § 423.773(c)(1)(iii).
85 42 U.S.C. § 1395w-114(a)(3)(B)(iii). The statute requires that these “re-determinations and appeals” be made in the same manner, and with the same frequency, that such re-determinations and appeals are made with respect to Medicaid eligibility determinations in the state.
87 See 42 U.S.C. § 1395w-114(a)(3)(B)(iv)(II) (referencing SSI process at 42 U.S.C. § 1383(c)(1)(A)). Note the precision with which Congress directed a particular appeals process; the
Suppose, however, that an applicant for the low-income subsidy applies for the subsidy through either the state Medicaid plan or through the Social Security Administration and is denied. Such applicants have statutorily-specified appeal rights for both re-determinations and appeals of adverse re-determination decisions. The question will then arise whether the unsuccessful applicant can obtain judicial review of that adverse decision. The answer to that question requires different analysis depending upon where the applicant applies for the subsidy. It is to that analysis that we now turn.

C. Judicial review of adverse Medicaid determinations

The intellectual analysis for determining whether or not judicial review in the federal court system is available to enforce the Medicaid entitlement consists of three prongs. The first is whether the applicant challenging a denial of the entitlement is able to seek judicial review at all, or whether they are merely a third-party beneficiary of the Medicaid state plan agreed to by the state and the federal government. Second, the applicant must have a statutory basis to secure enforcement. Finally, the relief that the applicant seeks must not violate the 11th Amendment to the United States Constitution, always implicated whenever a state is a potential defendant in the federal courts.

1. Third Party Beneficiary Analysis

Two recent court decisions raise the question whether a Medicaid beneficiary or potential beneficiary can challenge a decision to deny benefits made by a state Medicaid agency. Both rest on a belief that the Medicaid program is a contract between the federal government and the states and that an enrollee (or applicant) in the program is at best a third-party beneficiary of that contract unable to sue to enforce it. The first is Westside Mothers v. Havemann, [hereinafter, Westside Mothers].

State Medicaid plans must provide early and periodic screening, diagnostic, and treatment (so-called EPSDT) services to Medicaid-eligible individuals under the age of 21. The EPSDT benefit, as it is known, requires states to provide periodic physical examination, immunizations, laboratory tests and health education. In addition, the statute requires that appeals be managed in a manner “similar to the procedures described in the third sentence of” 42 U.S.C. § 1383(c)(1)(A). This precision will be relevant, see infra text following note 190, in the discussion of judicial review of an adverse decision by the Commissioner of Social Security.


42 U.S.C. § 1396d(a)(4)(B)(2005). These services are defined id. at § 1396d(r).

Id. at (c)(1).
benefit consists of eye examinations and eyeglasses.\textsuperscript{91} Teeth maintenance (dental services must also be covered.\textsuperscript{92} Finally, the benefit covers diagnosis and treatment of hearing disorders and hearing aids.\textsuperscript{93}

The plaintiffs, a patient advocacy organization and others, alleged in the suit that the state of Michigan had failed to provide (and failed to require managed care organizations providing Medicaid benefits for enrollees to provide) EPSDT services to children in the state under 21 years old.\textsuperscript{94} In a far-reaching decision, the U.S. District Court for the Eastern District of Michigan concluded that it lacked jurisdiction to hear the claim.\textsuperscript{95} Although there were several grounds for the court's decision, one of the more notable was its finding that "the Medicaid program is a contract between Michigan and the federal government, and Medicaid recipients are third party beneficiaries of that contract."\textsuperscript{96} In other words, because the Medicaid program was enacted pursuant to Congress' spending power under Article I, section 9 of the Constitution; it is "assuredly" a program "in the nature of a contract."\textsuperscript{97}

Having concluded that the Medicaid program is a contract between the states and the federal government the court went on to analyze common law contract enforcement principles. The court held that the federal government lacked the power to sue the states for specific performance of the Medicaid contract.\textsuperscript{98} It went on to find that no such right of action existed for third-party beneficiaries to that contract, either.\textsuperscript{99}

A 3-judge panel of the United States Court of Appeals for the Sixth Circuit overruled the District Court's decision in \textit{Westside Mothers}.\textsuperscript{100} It held, contrary to the decision of the district court, that Medicaid is "not merely [a] contract provision[ ]; [it is]\textsuperscript{101}

\begin{footnotes}
\item[91] Id. at (r)(2).
\item[92] Id. at (r)(3).
\item[94] \textit{Westside Mothers}, supra note 88, 133 F. Supp. 2d at 552.
\item[95] See id. (explaining that "neither jurisdiction nor a cause of action" is available to plaintiffs).
\item[96] Id. at 557.
\item[97] See id. at 561-63 (quoting \textit{Pennhurst State Sch. & Hosp. v. Halderman}, 451 U.S. 1, 17 (1981)) [hereinafter, \textit{Pennhurst}]. The court went on to note that spending power programs are not the "supreme law of the land" within the meaning of the Supremacy Clause of the Constitution.
\item[98] Id. at 558.
\item[99] See \textit{Westside Mothers}, supra note 88, 133 F. Supp. 2d at 579 (finding that the right did not exist). In reaching its conclusion, the court engaged in significant analysis as to whether 42 U.S.C. § 1983 provided a statutory basis to seek judicial enforcement of the Medicaid entitlement, and concluded that it did not. See id. at 579-81. The § 1983 analysis is crucial to understanding judicial enforcement and is discussed in greater detail. See infra text accompanying notes 115-29.
\item[100] \textit{Westside Mothers v. Havemann}, 289 F.3d 852 (6th Cir. 2002).
\end{footnotes}
Because the Medicaid program "has the binding force of law means that [it] . . . [is] not subject merely to doctrines of contract interpretation." Although the district court judge made much of the fact that the Supreme Court, in Pennhurst, compared Medicaid to a contract, it noted that the Supreme Court had, more accurately, described the program as "much in the nature of a contract." Hence, the Sixth Circuit concluded, Medicaid had some type of status that exceeded that or "merely" a contract.

To say that the district court decision in Westside Mothers was shocking to some is perhaps an understatement. It was not, however, a decision outside of the mainstream of judicial opinion. In Pharmaceutical Research and Manufacturers of America v. Walsh, [hereinafter PhRMA v. Walsh], we see why.

PhRMA v. Walsh involved a program enacted by the state of Maine intended to lower the price of prescription drugs purchased by Maine residents, especially those without insurance. To fund the program, the state imposed a "supplemental rebate" requirement on manufacturers who hoped to sell prescription drugs to Maine residents. Petitioner PhRMA challenged the Maine law as unconstitutional. They

101 Id. at 858.
102 Id.
104 See Westside Mothers, supra note 100, 289 F.3d 852, 857 (emphasis in original). See also id. at 858 (emphasizing the words "in the nature of").
105 See id.
108 See ME. REV. STAT. ANN. tit. 22, § 2681. See also PhRMA v. Walsh, supra note 107, 538 U.S. at 649 (noting that Maine’s program of discounted drugs open to all state residents).
109 See PhRMA v. Walsh, supra note 107, 538 U.S. at 651-52 (describing program). Under the Medicaid program, pharmaceutical manufacturers must provide rebates to the Secretary of Health and Human Services (HHS), who shares the rebates with the states. 42 U.S.C. § 1396r-8(a)(1). The rebate is generally equal to the greater of the excess of the manufacturer’s average sales price for the drug over the “best price” of the drug, or 15.1% of the AMP. Id. at § 1395r-8(c)(1), (2). The Maine program, in essence, extended this rebate requirement to sales of drugs to all participants in any publicly-supported financial assistance program in the state — i.e., to individuals who were not entitled to Medicaid. See PhRMA v. Walsh, supra note 107, 538 U.S. at 654 (describing Maine statute). Manufacturers that refused to pay the rebates were subject to a
argued that it was pre-empted by the federal Medicaid program, and that it violated the negative Commerce Clause.110

The Supreme Court of the United States rejected PhRMA's challenge to the Maine law.111 In a concurring opinion, Justice Thomas questioned whether PhRMA, as a third party, could sue to enforce the Medicaid statute.112 Adopting reasoning remarkably similar to the district court judge in Westside Mothers, Justice Thomas explained that in his view, a serious question existed as to whether PhRMA would be able to sue to enforce the Medicaid contract between Maine and the United States as a third party beneficiary to that contract.113 His opinion said that if he were presented with the argument, he "would give careful consideration" to it.114

2. Statutory Basis to Secure the Entitlement

The second step in the analysis of judicial review of adverse Medicaid decisions is whether there is a statutory basis to enforce the availability of a Medicaid benefit (or, in our case, a benefit whose availability is decided by a Medicaid official). That analysis begins with the decision of the Supreme Court of the United States in Wilder v. Virginia Hosp. Ass'n,115 [hereinafter, Wilder]. It also includes Justice Thomas' concurring opinion in PhRMA v. Walsh.

Wilder involved a group of hospitals that challenged a decision of the Medicaid agency of the state of Virginia to change reimbursement rates to those hospitals. A provision of the federal Medicaid statute, since repealed, provided that Medicaid rates of payment to institutional providers must be "reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities" that sought

requirement that, under the state's Medicaid program, their drugs would be subject to prior authorization. See id.

110 PhRMA v. Walsh, supra note 107, 538 U.S. at 650.

111 See id. at 668 (describing Court's holding that Maine law not pre-empted). At the very least, the Court suggested that until Maine had received approval from CMS to implement its program, PhRMA's challenge was premature.

112 See id. at 683 (Thomas, J. concurring in judgment) (explaining the Penhurst reasoning).

113 See id. (describing third party beneficiary enforcement of contract analysis). Third party beneficiaries may only sue to enforce a contract when they are the "intended beneficiary" of the contract. See id. (quoting Restatement (Second) of Contracts § 304 (1979)). PhRMA is not the intended beneficiary of the contract between Maine and the United States, according to Justice Thomas. Therefore, they cannot enforce it. Id.

114 Id.

to provide services to Medicaid beneficiaries. The Virginia rate setting methodology grouped hospitals into "peer group[s]" and capped reimbursement at the median per-diem cost for hospitals in each peer group. The effect, of course, was to reduce reimbursement to those hospitals whose costs were above the median per-diem.

The hospitals challenged the Virginia rate setting methodology. In their view, that methodology did not ensure that rates were "reasonable and adequate to meet the costs" of efficiently operated facilities that sought to provide services to Medicaid beneficiaries. Accordingly, they filed suit against state officials in U.S. District Court for the Eastern District of Virginia seeking declaratory and injunctive relief blocking the new rates. They also sought an order directing that the state establish a new rate setting methodology and temporarily increase payment rates to them.

The providers sought to enforce their putative right to higher reimbursement using 42 U.S.C. § 1983. That statute provides a cause of action for "[T]he deprivation of any rights, privileges, or immunities secured by the Constitution and laws" of the United States. Both the District Court and the U.S. Court of Appeals for the Fourth Circuit dismissed the State's motion to dismiss or in the alternative motion for summary judgment. In those courts' view, health care providers can use 42 U.S.C. § 1983 to...

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117 See Wilder, supra note 115, 496 U.S. at 503 (explaining effect of Virginia methodology).

118 See id. at 503-04.

119 See id.

120 42 U.S.C. § 1983. The full statute provides in relevant part:

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State of Territory or the District of Columbia, subjects or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress...

sue state officials in federal court to ensure compliance with the Medicaid program.

In a 5 – 4 decision, the Supreme Court of the United States affirmed. The Court applied its two-pronged § 1983 analysis, articulated most recently in *Wright v. Roanoke Redevelopment and Hous. Auth.* [122] [hereinafter *Wright*]. Applying the first prong, the Court found that the Medicaid statute – and the Boren Amendment in particular – created enforceable rights. [124] The Amendment, the Court held, was “cast in mandatory rather than precatory terms” and compliance with the Amendment was a prerequisite to obtaining federal funds. [125] Moreover, past history – dating back to the statute as it existed prior to the adoption of the Boren Amendment – showed clearly that states understood that they could be sued by providers for failure to comply with the terms of the Medicaid statute. [126]

Turning to the second prong, the Court concluded that Congress had not foreclosed enforcement of the Medicaid statute in federal court, noting that there was “little merit” in the state’s argument on this issue. [127] It found that the Medicaid statute created no alternative, comprehensive means to obtain private judicial or administrative enforcement of the statute’s requirements. [128] The state’s own administrative system was not such an alternative means. Hence, the only recourse for providers was 42 U.S.C. § 1983. [129]

3. *Eleventh Amendment Analysis*

Adopted shortly after the adoption and ratification of the Bill of Rights, the Eleventh Amendment provides simply that “The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted in the several states of the United States.” [120] As applied in state courts, it means that a state may be sued in its courts only with its consent. [121] Hence, in federal courts, the Amendment provides a basis for immunity from suit against a state when a claim is for damages for actions taken by a state or its officials in their official capacities. [122] To decide whether a state is immune, the court must determine whether the case presents a controversy of the type of which the federal courts had original jurisdiction. [123] The Supreme Court has held that original jurisdiction in this context exists where the cause of action arises under federal law, whether or not there is a corresponding claim under state law. [124]

123 Under that analysis, a plaintiff may seek relief using 42 U.S.C. § 1983 if (1) the statute under review creates enforceable rights and (2) Congress has not foreclosed enforcement in the statute under review.
124 Wilder, 496 U.S. at 509-10.
125 Wilder, 496 U.S. at 512.
126 See id. at 516 – 19 (detailing history of statute prior to enactment of Boren Amendment). See also id. at 516 (listing federal litigation prior to Boren Amendment).
127 Id. at 520.
128 Id. at 521-22.
129 Justice Thomas has questioned this reasoning. See PhRMA v. Walsh, supra note 107, (noting that private parties may only utilize statute when able to demonstrate an “unambiguously conferred right.”) (quoting Gonzaga Univ. v. Doe, 536 U.S. 273, 283 (2002)). Justice Thomas questions whether such a right is unambiguously conferred by the Medicaid statute. See id.
against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.”

The Amendment was enacted to reverse the result reached by the Supreme Court of the United States in *Chisolm v. Georgia*. On its face, the Amendment precludes federal jurisdiction over claims “against one of the United States by Citizens of another State. . . .” However, in 1890, the Supreme Court of the United States ruled that the Amendment also precluded claims against a state by its own citizens. It is therefore now clear that the Eleventh Amendment’s vast exercise of sovereign immunity poses an almost insurmountable obstacle whenever a state is a defendant in federal court.

There are exceptions to the seeming broad sweep of Eleventh Amendment

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130 U.S. Const. amend. XI.

131 *Chisolm v. Georgia*, 2 U.S. (2 Dall.) 419 (1793). The underlying case involved a dispute over a contract made between a citizen of South Carolina and the state of Georgia for supplies provided during the Revolutionary War. Article III of the Constitution clearly contemplates the prospect of diversity jurisdiction. *See US Const. Art. III, § 2, cl. 1* (conferring jurisdiction on federal courts to hear “Controversies . . . between Citizens of different States”). Article III also conferred jurisdiction on federal courts to hear “Controversies . . . between a State and Citizens of another State.” *See id. Chisolm* was brought pursuant to the latter conferral of diversity jurisdiction, and the Supreme Court of the United States granted jurisdiction. *See Chisolm, 2 U.S. (2 Dall.) at 452* (holding that by ratifying Constitution, Georgia consented to suit). The Court’s decision was obviously unpopular, given that the Eleventh Amendment, which overruled it, was ratified less than two years after *Chisolm* was decided.

132 U.S. Const. amend. XI (emphasis added).

133 *Han v. Louisiana*, 134 U.S. 1 (1890). *Han* was the culmination of years of litigation that arose after the Civil War, when some of the southern states that had seceded from the Union defaulted on revenue bonds that they had issued after the war. Citizens of states that had defaulted on the bonds brought suit against those states in federal court, taking the position that the states had impermissibly “impair[ed] the Obligation of Contracts,” prohibited under the Constitution. *See U.S. Const. Art. I, § 10, cl. 1* (prohibiting states from enacting any “Law impairing the Obligation of Contracts”). Hence, unlike *Chisolm*, *supra* note 131, where the plaintiffs had brought suit under the Article III grant of diversity jurisdiction, in *Han*, where there was no diversity of citizenship, the plaintiffs invoked federal question jurisdiction granted by Article III. *See Han, 134 U.S.* at 9 (explaining basis for jurisdiction). Nevertheless, and despite the apparent plain language of the Eleventh Amendment, the Supreme Court of the United States held that the Amendment also precluded suit against a state even by its own citizens. *See Han, 134 U.S.* at 15 (explaining “absurdity” of view that Congress would have barred suits against states by non-residents, but not residents). The Court said that it was clear that the “shock of surprise throughout the country” after the *Chisolm* decision made clear that Congress and the states did not intend to make defendants of unwilling States, regardless of whether the plaintiffs were from other states or the state’s own citizens. *See Han, 134 U.S.* 1, 11 (1890).
immunity.

For one, states may waive immunity and consent to suit in federal court. Congress may also withdraw immunity. Congress did precisely that in 1975 in the Medicaid program when it required states to waive Eleventh Amendment immunity from suit as a condition of participation in the Medicaid program. In addition, suits against state officials acting in their official capacity, where the plaintiff seeks equitable (such as injunctive relief) only, and where the state action is alleged to be a violation of federal law, may be heard in federal court notwithstanding Eleventh Amendment immunity.

As a result, the Eleventh Amendment is always implicated whenever an individual challenges an action by a state Medicaid agency in federal court. Indeed, in Westside Mothers, infra, the U.S. District Court for the Eastern District of Michigan flatly held that the Eleventh Amendment precluded the plaintiffs' lawsuit. That portion of the District Court's decision was, however, overturned by the Sixth Circuit. As a result, so long as a challenge to a state Medicaid action is filed against the state official acting in his official capacity rather than the state itself, and the relief sought is prospective only, the Eleventh Amendment would not appear to be a bar to federal court jurisdiction over the claim.

D. Judicial Review of Adverse Determinations by Medicare and Social Security

The analysis regarding the availability of judicial review under both the Medicare

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134 See Gunter v. Atl. Coast Line R.R., 200 U.S. 273 (1906) (holding that states may disclaim Eleventh Amendment immunity by enactment of legislation). That intent, however, must be "stated by the most express language or by such overwhelming implication" so that there is no other possible interpretation of the state's intent. Port Auth. Trans-Hudson Corp. v. Feeney, 495 U.S. 299, 305-06 (1990).

135 Pub. L. No. 94-182, § 111, 89 Stat. 1054 (1975). States that refused to do so would have suffered a reduction in Medicaid payments of 10%. See id. Not surprisingly, the law was exceedingly controversial; it was repealed the next year. See Pub. L. No. 94-552, 90 Stat. 2540 (1976).

136 See also Ex parte Young, 209 U.S. 123 (1908); see also Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981) (holding federal jurisdiction only proper where complaint alleges violation of federal, not state, law).

137 See Westside Mothers, supra, note 88, 133 F. Supp. 2d at 559-60; See also the text accompanying n. 89-99, infra.

138 See Westside Mothers, supra note 100, 289 F.3d at 861-63 (reversing District Court's Eleventh Amendment analysis).
and Social Security programs is equally interesting. Here, our discussion begins with 42 U.S.C. § 405(h). After that, it is important to discuss other relevant provisions applicable in both the Social Security and Medicare programs. Finally, it is necessary to analyze whether these inter-related statutory provisions act as a flat preclusion of judicial review of decisions made by the Commissioner of Social Security or the Medicare program or whether it acts as a channeling requirement only.

1. Statutory Framework

In relevant part, section 405(h) makes clear that:

[n]o findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28, United States Code, to recover on any claim arising under this title.\(^\text{139}\)

On its face, then, the statute provides that the only means to obtain review of a factual determination or decision by the Commissioner of Social Security is through processes specified within the Social Security Act. Further, the section clearly precludes federal question jurisdiction in the federal courts over any claim filed against the Commissioner of Social Security, if the claim "aris[es] under" title II of the Act.\(^\text{140}\)

Subsection (g) of section 405 is also relevant to this analysis, because it specifies the sole basis for a process to obtain judicial review of a decision by the Commissioner of Social Security: i.e., the process that is "herein provided" within title II. That subsection instructs that:

[ach]y individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district


\(^{140}\) Title II of the Social Security Act is the statute implementing Social Security program. See 42 U.S.C. § 401(a) (creating Social Security trust fund). Title XVIII of that Act implements the Medicare program; Title XIX, the Medicaid program. See 42 U.S.C. § 1395 et. seq.
in which the plaintiff resides, or has his principal place of business, or,
if he does not reside or have his principal place of business within any
such judicial district, in the United States District Court for the
District of Columbia. . . . The court shall have power to enter, upon the
pleadings and transcript of the record, a judgment affirming, modifying,
or reversing the decision of the Commissioner of Social Security, with
or without remanding the cause for a rehearing. . . . The judgment of
the court shall be final except that it shall be subject to review in the
same manner as a judgment in other civil actions. 141

Reading this subsection in conjunction with subsection (h), it seems clear that
adverse decisions of the Commissioner of Social Security may be reviewed in federal
court, but not pursuant to federal question jurisdiction. Rather, that jurisdiction is
conferred by the first sentence of subsection (h) and subsection (g).

The analysis becomes slightly more complicated when determining whether
judicial review is available in the Medicare program. Section 405(h) has been
incorporated into the Medicare program. 142 Section 405(g) has not. 143 Therefore, in
order to determine whether judicial review is available under the Medicare program,
some other provision of title XVIII must authorize it. If it is not expressly authorized,
section 405(h), through its incorporation into title XVIII, seems to preclude jurisdiction.

There are, in fact, several places where the Medicare program will allow judicial
review of adverse decisions. Beneficiaries may challenge a denial of entitlement to
Medicare benefits and the amount of those benefits. 144 They may also challenge local
and national coverage determinations. 145 Institutional providers may challenge
reimbursement determinations made by Medicare’s claims processors. 146 An
institutional provider may also challenge a determination by survey agencies that it is out

143 See id. (excluding from list subsection (g) of section 405).
144 See 42 U.S.C. § 1395ff(a)(1)(A), (B) (2005) (listing decisions that may be subject to “initial
determination” by the Secretary). Adverse decisions may be challenged in federal court because
42 U.S.C. § 405(g) is expressly made applicable to such appeals. Id. at subsection (b)(1)(A).
determinations) and § 1395ff(f)(2)(A)(iv) (providing for judicial review of local coverage
determinations).
regarding payment decisions).
of compliance with Medicare's conditions of participation.147

2. Judicial Review Outside of the Tightly-Crafted Framework

These inter-related and tightly-crafted statutory provisions seem to provide a roadmap to enable a party to eventually obtain judicial review under the Medicare program after first satisfying an internal administrative procedure. There may be occasions, however, where the statute does not speak precisely to the question on which a party seeks review, leaving no administrative process at all and judicial review potentially foreclosed by the application of § 405(h). There may be other occasions where compliance with the statute's administrative appeals process may be so burdensome that to require a party to navigate those processes would be arguably unfair. Not surprisingly, these occasions have led to litigation that has had significant impact on the operation of the Medicare program.

An example of an incident where the statute appeared not to provide an administrative procedure that would ultimately lead to judicial review of adverse agency action arose in Bowen v. Michigan Academy of Family Physicians,148 [hereinafter Michigan Academy]. In Michigan Academy, a group of physicians challenged a regulation issued by the predecessor agency to CMS that established fee schedule amounts for physician services. Fee amounts varied depending upon whether or not the physicians were board certified; those who were not received lower fees.

In defending the lawsuit, the Secretary of Health and Human Services argued that the statute in two places foreclosed judicial review of the regulation. The Secretary first argued that 42 U.S.C. § 1395ff foreclosed judicial review. That statute, as it read at the time of the decision, authorized judicial review of challenges to “the amount of benefits under [Medicare] Part A.”149 The regulation at issue in Michigan Academy, however, challenged the amount of benefits available under Medicare Part B. The Secretary argued that because the statute did not mention challenges to benefits available under Medicare Part B, judicial review was impliedly foreclosed. The Secretary argued that the Supreme Court's earlier decision in United States v. Erika,150 [hereinafter Erika], which had found judicial review of determinations of the amount of benefits available under Part B foreclosed under 42 U.S.C. § 1395bb, was dispositive of the matter.

The Supreme Court of the United States disagreed, however. At the outset, the Court noted that there is a "[S]trong presumption that Congress intends judicial review of administrative action."\textsuperscript{151} It then found a basis to distinguish its earlier holding in \textit{Erika}. In \textit{Erika}, the Court held that judicial review was foreclosed because if every Medicare beneficiary were able to challenge the "amount" of their benefits, it would "overload[ ] the courts with trivial matters, a consequence that would unduly tax the federal court system with little real value to the participants in the system."\textsuperscript{152} In \textit{Michigan Academy}, by contrast, the physicians were not challenging the amount of benefits, but rather, the validity of a regulation. The Court found that distinction highly relevant.\textsuperscript{153}

The Court also rejected the Secretary's argument that 42 U.S.C. § 405(h) foreclosed judicial review. It described the Secretary's position on that question as "extreme" and one that the Court was unwilling to adopt "without a showing of clear and convincing evidence" that such was the intent of Congress.\textsuperscript{154} The Secretary, however, was only able to point to Congress' intent to foreclose judicial review of minor claims. But noting that those claims are at least subject to administrative review by Medicare's contractors, the Court noted that the Secretary's position was that administrative review was available for minor claims, but that no review was available at all "of substantial statutory and constitutional challenges to the... administration of Part B of the Medicare program."\textsuperscript{155} This, the Court held, was an untenable position. It rejected the Secretary's argument, and held that neither § 1395ff(b) nor § 405(h) foreclosed judicial review of the Secretary's regulation implementing physician payments.\textsuperscript{156}

An example where the administrative procedure contemplated by the statute posed a burdensome process such that requiring a party to navigate those processes would be unfair arose in \textit{Shalala v. Illinois Council on Long Term Care, Inc.},\textsuperscript{157} (2000) [hereinafter \textit{Illinois Council}]. In \textit{Illinois Council}, the challengers were a group of nursing facilities that challenged regulations issued by the Department of Health and Human Services designed to implement 42 U.S.C. § 1395i-3 and 42 U.S.C. § 1396r. At the

\begin{itemize}
\item \textsuperscript{151} \textit{Michigan Academy}, supra note 147, 476 U.S. at 670.
\item \textsuperscript{152} \textit{Id.} at 675 (internal quotation marks and citations omitted).
\item \textsuperscript{153} \textit{See id.} at 676 (holding Congress did not intend foreclosure of judicial review of "method" by which Part B benefits "are computed").
\item \textsuperscript{154} \textit{Id.} at 680-81 (internal quotation marks omitted).
\item \textsuperscript{155} \textit{Michigan Academy}, supra note 147, 476 U.S. at 680.
\item \textsuperscript{156} \textit{See id.} (holding that § 405(h) did not bar jurisdiction).
\item \textsuperscript{157} Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000).
\end{itemize}
outset, the Supreme Court described the "two competing jurisdictional routes" that the challengers could have taken to obtain judicial review of their claims. The first was general federal question jurisdiction under 28 U.S.C. § 1331. The second was 42 U.S.C. § 1395cc(h)(1), which allows institutional providers to obtain judicial review of a finding of non-compliance with Medicare’s conditions of participation only after the Secretary “has determined” that such a finding is accurate.

As was the case in *Michigan Academy*, the Secretary again argued that 42 U.S.C. § 405(h) foreclosed judicial review of the nursing homes’ claims until after those claims had been channeled through the agency process. The nursing homes, however, argued that *Michigan Academy* had changed the analysis. In their view, *Michigan Academy* stood for the proposition that the foreclosure of judicial review in § 405(h) only applied to “amount determinations” and not to substantive challenges to the agency’s regulations. They also argued that even if *Michigan Academy* could not be read so broadly, they still qualified for immediate access to judicial review because the absence of any review would effectively mean no review at all. The Supreme Court, however, rejected both arguments.

As to the first – that *Michigan Academy* created some sort of distinction between “amount determinations” and procedural or constitutional challenges to Medicare regulations – the Court rejected such a broad interpretation of its earlier holding. It said instead that “it is more plausible to read *Michigan Academy* as holding that . . . § 405(h) [does not apply in the Medicare program] where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.” But here, by contrast, the providers did have an opportunity for review. That means of review is specified in 42 U.S.C. § 1395cc(h)(1).

That left the court with the providers’ second argument: that as a practical matter, the Secretary’s proposed process for conducting nursing home surveys meant that nursing homes would, in fact, have no review of an adverse survey and that as a result, they were entitled to immediate review. As the providers saw the state of things,

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159 See supra note 146.
160 See 42 U.S.C § 1395cc(b)(2)(2005).
162 See id. at 20 (describing alternative argument).
163 See id. at 16-20 (rejecting providers’ argument).
164 See id. at 19 (emphasis in original).
once a nursing home was found deficient in a survey based upon the challenged regulation, their Medicare participation would be terminated. Because nursing homes rely on Medicare funding, they could not afford to have that funding terminated and that the practical result of an adverse survey was that they would either have to accept a penalty they believed was invalid, or they would have to lose Medicare certification and close their doors.

Again, the Court rejected this argument. It said that “[t]he short, conclusive answer to these contentions is that the Secretary denies any such practice.”\textsuperscript{165} If a nursing home is adjudged deficient by a surveyor, it has a process to challenge the CMS regulations and face a sanction short of termination from the program; furthermore, the Court recited a CMS statistic that only 25 out of more than 13,000 nursing homes were terminated in the year that the challenged regulations became effective.\textsuperscript{166} Therefore, because it was not at issue here, the Court left open the question whether an agency practice that forced aggrieved parties to abandon legitimate challenges to agency action practically denied judicial review; it merely held that that in this case, the challengers did not fit into the exception that Michigan Academy created.\textsuperscript{167}

Two later cases have considered this Michigan Academy “exception.” In National Association of Psychiatric Health Systems v. Shalala,\textsuperscript{168} the U.S. District Court for the District of Columbia applied the exception to another regulation promulgated by CMS. The regulation at issue, issued in response to press reports of deaths that occurred when patients in psychiatric facilities were placed in involuntary restraints and seclusion, required a physician to conduct a face-to-face assessment of a patient placed in restraints within one hour of the initiation of the intervention.\textsuperscript{169} Like the nursing homes in Illinois Council, hospitals that violated the so-called “one hour rule” would be adjudged deficient and out of compliance with a condition of participation.\textsuperscript{170} Unlike the nursing homes in Illinois Council, however, the hospitals that challenged the one-hour rule had no chance to incur a minor penalty and challenge the regulation.\textsuperscript{171}

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\textsuperscript{165} See \textit{Illinois Council}, supra note 156, 529 U.S. at 22.
\textsuperscript{166} See id. (citing statistic).
\textsuperscript{167} See id. at 25. The Court contemplated that some agency procedures might turn a purported channeling requirement into a preclusion of judicial review. See id. at 22-23. It held, however, that the CMS procedure at issue here was not such a policy.
\textsuperscript{171} See \textit{NAPHS}, supra note 167, 120 F. Supp. 2d at 38.
\end{flushright}
Rather, the sanction for violation of the rule was termination of the hospital’s agreement to participate in the Medicare program – economic suicide, in the words of the plaintiff hospitals. 172

The court found this distinction highly relevant. It concluded that this was precisely the “exception” that Michigan Academy and Illinois Council created. 173 In Illinois Council, the channeling requirement that the statute contemplated did not entirely foreclose judicial review. To be sure, it delayed it – but ultimately, providers could obtain judicial review. Here, by contrast, hospitals faced the practical denial of judicial review because to violate the one-hour rule meant that they faced possible exclusion from the Medicare program with no opportunity for an intervening, mitigating step. Therefore, access to judicial review without agency channeling was permissible. 174

Later, in American Lithotripsy Society v. Thompson, 175 [hereinafter American Lithotripsy], the same court again had occasion to apply the Michigan Academy/Illinois Council exception. In American Lithotripsy, plaintiffs challenged a CMS interpretation of the “self-referral” law. 176 Under the CMS interpretation, physicians that had an ownership interest in entities that provided lithotripsy services could not refer Medicare or Medicaid patients to those entities. 177 The American Lithotripsy Society challenged that regulation under the Administrative Procedures Act. Before the court could hear that challenge, of course, it had to determine whether it had subject matter jurisdiction to hear the claim in the first place; as it had in NAPHS, the government argued that 42 U.S.C. § 405(h) precluded judicial review of the claim. 178

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172 See id. at note 4. Moreover, the Secretary did not dispute this characterization. Id. at note 5.
173 See id. at 39.
174 See id. Unfortunately for the hospitals, the court ultimately ruled against them on substantive grounds. At heart, the hospitals’ argument was that CMS had violated the Administrative Procedures Act in the sense that the final rule promulgated by CMS was not a logical outgrowth of the proposed rule; the court disagreed. See id. at 40 Hence, although the hospitals were able to obtain judicial review over their claim, they were unable to convince the court that they should prevail on the merits.
176 The “self-referral” statute prohibits physicians from submitting claims to Medicare or Medicaid for services provided to patients who those physicians refer to certain entities providing “designated health services” in which they or their families have a financial interest, unless an exception applies. See generally, 42 U.S.C. § 1395nn(a) (2005) (imposing general prohibition). See also 42 U.S.C. § 1395nn(h)(6) (2005) (defining “designated health services”).
177 Although lithotripsy services are not “designated health services” under the statute, the CMS regulation at issue took the position that those services were “inpatient and outpatient hospital services” which are designated health services. See 42 U.S.C. § 1395nn(h)(6)(K) (2005).
The court rejected the government’s argument. As it had in *NAPHS*, the court found a distinction between the penalties potentially faced by the nursing homes in *Illinois Council* and the penalties faced by the lithotripsy providers challenging the self-referral law here. In *Illinois Council*, a nursing home faced the potential of a small fine before it could challenge the Secretary’s regulation. Here, by contrast, physicians with investment interests in lithotripsy providers faced fines of $15,000 per claim; the average physician investor would submit hundreds of claims per year. Therefore, the potential harm to a physician investor seemed more like the “economic suicide” described by the court in *NAPHS* than the minor fine potentially faced by the nursing homes in *Illinois Council*.

Reading *Michigan Academy* and *Illinois Academy* together with the two lower court decisions that came after *Illinois Council*, it appears likely that section 405(h) functions now more as a channeling requirement than a complete bar to federal question jurisdiction. *Illinois Council* clearly left open the door to cases where section 405(h) would not operate as an absolute bar to federal question jurisdiction. The Court suggested that “it is more plausible to read *Michigan Academy* as holding that . . . § 405(h) [does not apply in the Medicare program] where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.” Such a case may be rare indeed (although given the fact that the U.S. District Court for the District of Columbia found two examples in the space of two years, one may question how “rare” such cases are). Nevertheless, in all but such a case, this channeling requirement is a prerequisite for federal court review.

IV. Discussion

A. Medicaid Review

If an applicant for the low-income subsidy applies for the subsidy at a local Medicaid office rather than at the Social Security Administration, then the question will arise whether judicial review is available to an applicant who receives an adverse decision from that agency. We therefore apply our three-pronged analysis to answer the question. Before doing so, however, it bears note that the factual question is not

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181 See id.
182 See *Illinois Council*, supra note 156, 529 U.S. at 19 (emphasis in original).
precisely the same as would occur if the challenge were to the denial of a Medicaid benefit under title XIX of the Social Security Act. With the low-income subsidy, the benefit at issue is not a Medicaid benefit; it is a Medicare benefit. The decision regarding eligibility for the benefit, however, rests with the state Medicaid agency, not the Medicaid program. As a result, the analysis, while similar, is not identical.

The first question is whether or not the applicant can bring the claim in her own right, or whether the applicant is a third-party beneficiary to a contract between the state Medicaid agency and the federal government and unable to bring the claim on her own. As a factual matter, there is no contract to analyze. Under the traditional Medicaid program, the Medicaid agency files a state plan with the federal government describing how it will operate its Medicaid program, and the federal government will either approve or disapprove the plan. In theory, that state plan could be viewed as a "contract" between the federal government and the states. Under the low-income subsidy, however, the state plan for medical assistance will not have to include coverage of the subsidy, since it is funded entirely by the federal government. The role of the state is limited to processing the application. As a legal matter, even if the role of the state were more involved, and the state were required to partially fund the subsidy, we have seen that the courts seem to have rejected an analysis where Medicaid beneficiaries are third-party beneficiaries to a "contract" between the state and federal government who are unable to enforce that contract.

The second question is whether there is a statutory basis to enforce the claim. We learned in *Wilder*, supra, that there is such a basis if a state official acting in their official position deprives a person "of any rights, privileges, or immunities, secured by the Constitution and laws" of the United States. As was seen in that case, the reviewing court will allow 42 U.S.C. § 1983 to be used as a basis to enforce the claim if: (1) the federal statute creates enforceable rights and (2) Congress has not foreclosed enforcement in the statute itself.

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183 See 42 U.S.C. § 1396 (2005) (providing funding only to states that have submitted, and have had approved, state Medicaid plans).
The first prong is satisfied if the federal statute was “intended to benefit the putative plaintiff” and does not “reflect[] merely a congressional preference for a certain kind of conduct” or unless the plaintiff’s interest “is too vague or amorphous” for the courts to enforce that interest. Applying that test, it seems likely that a court would find that the low-income subsidy created enforceable rights. Clearly, the subsidy is intended to benefit low-income individuals who will have difficulty in affording drug coverage under Part D. Moreover, availability of the subsidy is more than a “congressional preference”; the subsidy must be made available to qualified applicants. Under the statute, such an applicant “is entitled” to the subsidy. In addition, the subsidy is not “vague or amorphous”; to the contrary, it is meticulously described in the statute.

As to the second prong, Congress has not foreclosed enforcement of the subsidy. To the contrary, Congress foresaw that there might be disputes regarding eligibility for the subsidy. It provided that, with respect to applications processed by state Medicaid programs, re-determinations and appeals of those applications shall be conducted “in accordance with ... the manner in which” appeals of traditional Medicaid eligibility are made within the state. Since appeals of traditional Medicaid eligibility can be ultimately heard in federal court, allowing appeals of low-income subsidy determinations to be heard in federal court would be the same “manner in which” those Medicaid appeals are heard. Hence, far from foreclosing enforcement of the statute in federal court, Congress seems to have contemplated enforcement of it there.

Finally, the third question is whether the 11th Amendment to the United States Constitution would in some way act as a barrier to enforcement of a denial of an application for subsidy assistance in federal court. As we have seen above, it surely would if the unsuccessful applicant sought monetary damages from the state agency that denied the application. However, to the extent that the unsuccessful applicant complied with the ex Parte Young doctrine and sued a named state official for prospective or injunctive relief only, such an applicant could successfully navigate the 11th Amendment minefield that would otherwise exist.

B. Medicare Review

We turn now to the question whether judicial review would be available to an

188 See Wilder, supra note 115, 496 U.S. at 509 (explaining first prong of the test) (internal quotation marks and citations omitted).
190 See id. at paragraph (3)(A)(iii).
individual who applies for the low-income subsidy with the Social Security Administration, rather than a local welfare office. The analysis here is different than the Medicaid analysis. The applicable analysis here tracks the analysis that would be used to determine whether judicial review is available under the Medicare program. The first question is whether the MMA, on its face, precludes judicial review of the low-income subsidy. If the statute does not preclude judicial review, the second question is whether 42 U.S.C. § 405(h) can be read to preclude judicial review, in light of the Supreme Court’s decisions in *Michigan Academy* and *Illinois Council*. The final question is whether the agency has agreed to provide for judicial review.

The first step in the analysis – whether the statute expressly precludes judicial review – is not as straightforward as it might appear. The statute instructs that the Commissioner of Social Security “shall establish procedures for appeals of [eligibility] determinations that are similar to the procedures described in the third sentence of § 1383(c)(1)(A).”191 That sentence, in turn, provides that

> the Commissioner of Social Security shall provide reasonable notice and opportunity for a hearing to any individual who is or claims to be an eligible individual or eligible spouse and is in disagreement with any determination under this title with respect to eligibility of such individual for benefits, or the amount of such individual’s benefits, if such individual requests a hearing on the matter in disagreement. . . .192

Section 1383(c)(3), and not the third sentence of section 1383(c)(1)(A), then provides for judicial review “as provided in section 405(g).”193

The question, then, is whether the statute has effectively foreclosed judicial review by referencing only the third sentence of the SSI internal appeals process in section 1383(c)(1)(A) and not referencing the availability of judicial review in section 1383(c)(3). On the one hand, one could make the argument that Congress made an express decision to foreclose judicial review by not referencing the later section. On the other hand, one could view the language of 42 U.S.C. § 1395w-114(a)(3)(B)(iv)(II), that

191 *Id.* at clause (iv)(II) (emphasis added).
192 42 U.S.C. § 1383(c)(1)(A) (2005). Section 1383 relates to the Supplemental Security Income (SSI) program, and the statutory reference to “this title” is to title XVI of the Social Security Act, where the SSI program is codified.
193 *Id.* at subsection (c)(3). Recall that 42 U.S.C. § 405(g) provides for judicial review of adverse Social Security benefit determinations after an initial internal administrative process. *See infra* note140. That section has not been incorporated into the Medicare program. *See infra* text accompanying note 142.
only requires an appeals process that is "similar to" the SSI appeals process, as an
ingestation that Congress did not intend for the Commissioner of Social Security to be
tied only to that appeals process.

Because the answer is not clear, we move to the second prong of our analysis to
see if the decisions of *Michigan Academy* or *Illinois Council* provide any guidance. And
indeed, it seems that they do. In *Michigan Academy*, the Supreme Court noted the "strong
presumption that Congress intends judicial review of administrative action."194 The
Court went on to hold that there should be no presumption of foreclosure of judicial
review "without a showing of clear and convincing evidence" that Congress intended to
do so.195 One could argue that Congress intended to foreclose judicial review because
of the precise reference to the "third sentence" of the SSI appeals process without a
reference to the provision for judicial review. That argument, however, is similar to the
argument that the government advanced in *Michigan Academy*: that because the statute
allowed for appeals of Medicare part A determinations but left silent the question
whether appeals were available for Medicare part B determinations, the Court should
presume that there was no judicial review of part B appeals. But the Supreme Court
rejected that argument in *Michigan Academy*, and it seems that decision would control the
result on this issue.

But that is not all. Since the Supreme Court's decision in *Michigan Academy*,
Congress has expressly shielded many areas of the Medicare program from judicial
review.196 The fact that Congress did not expressly provide for preclusion of judicial
review of low-income subsidy determinations by the Commissioner of Social Security
would probably be fatal, under the reasoning of *Michigan Academy*, to an argument that
there is no judicial review of those determinations.

195 Id. at 680-81.
Geographic Classification Review Board from judicial review); 42 U.S.C. § 1395f(g)(12)(2005)
(forclosing judicial review of many components of outpatient prospective payment system); and
nursing facility reimbursement system). See also 42 U.S.C. § 1395w-3a(g)(2005) (precluding
judicial review of most components of average sales price methodology for reimbursement of
Medicare part B drugs) and MMA, supra note 1, § 105(c)(4)(A) (precluding judicial review of CMS
decisions not to contract with prescription drug discount card sponsors). Given the enactment
of the MMA preclusions, in particular, one could obviously argue that if Congress wanted to
preclude judicial review of provisions of the MMA, it knew how to do so, and its failure to do so
in the low-income subsidy context falls short of the "clear and convincing evidence" standard
that the Supreme Court would need to find judicial review foreclosed. See *Michigan Academy*, supra
note 147, 476 U.S. at 680-81.
Although in its later decision, *Illinois Council*, the Supreme Court perhaps narrowed the holding of *Michigan Academy*, it certainly did not overrule the decision. Rather, the Supreme Court of the United States said only that "it is more plausible to read *Michigan Academy* as holding that... § 405(h) does not [apply in the Medicare program] where application of § 405(h) would not simply channel review through the agency, but would mean no review at all."\(^{197}\) And, in the low-income subsidy context, arguing that there is no judicial review of a decision denying the subsidy to an applicant would effectively apply § 405(h) for that purpose, rather than for the purpose of mere channeling. Section 405(h) now most likely stands as a channeling requirement only: an unsuccessful applicant must go through the administrative process contemplated by the "third sentence of § 1383(c)(1)(A)"\(^{198}\) but gets judicial review at the end of that process.

Finally, we examine the intent of the agency implementing the statute. The Social Security Administration has proposed to take the position that judicial review is available of adverse decisions regarding availability of the subsidy.\(^{199}\) Therefore, that agency, if it adopts its proposed rule in final form, will provide a dissatisfied applicant access to judicial review.

V. Conclusion

The addition of an outpatient prescription drug benefit to the Medicare program is a long-awaited and much-needed improvement. In enacting the benefit, Congress and the President were clearly most concerned with ensuring that low-income Medicare beneficiaries would be able to obtain prescription drug coverage at minimal out-of-pocket cost; those beneficiaries were those most likely to be without prescription drug coverage under the traditional Medicare program. For that reason, the legislation includes extremely generous subsidies for low-income Medicare beneficiaries, effectively eliminating or drastically subsidizing premiums and most cost-sharing. This is an important benefit for those low-income individuals especially and one that should be welcomed by everyone concerned with health law and policy.