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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF ALASKA**

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| UNITED STATES OF AMERICA Ex rel. Law Project for Psychiatric Rights, an Alaskan non-profit corp., | ) | |
| Plaintiff, | ) | Case No. 3:09-cv-0080-TMB |
| OSAMU H. MATSUTANI, MD., et al., | ) | |
| Defendants. | ) | |

**REPLY IN SUPPORT OF**
**MOTION TO DISMISS UNDER RULE 12(B)(6) (DKT. #92)**

## I. INTRODUCTION AND STANDARD OF REVIEW

A court must dismiss a complaint that fails to "state a claim to relief that is *plausible* on its face."[1] "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."[2] Applying the plausibility standard at the pleading stage is particularly appropriate when the law requires proof of falsity for the claim to succeed.[3] PsychRights's claims cannot meet the plausibility standard, and therefore must be dismissed.

PsychRights advances a novel theory of FCA liability in this case. It alleges that *all* claims submitted to the Alaska Medicaid and Denali KidCare (CHIP) programs for a prescription drug's off-label use that is not supported by one of three "compendia" specified in the Medicaid rebate law are *per se* false because, according to PsychRights, federal Medicaid law prohibits states from covering such non-compendium uses.

This claim cannot meet the "plausibility standard" for two reasons. First, PsychRights cannot show that the Medicaid and CHIP claims were *per se* false or fraudulent, regardless of what federal law allows, because every claim potentially at issue was submitted *to the State of Alaska*, for payment *by the State of Alaska*, under a State Plan *approved by the federal government*, and pursuant to *state laws* that PsychRights concedes authorize the claims to be presented and paid. Second, PsychRights misinterprets federal law: the Social Security Act does not prohibit states or the federal government from paying for non-compendium prescriptions.

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[1] *Bell Atlantic Corp. v. Twombley*, 550 U.S. 544, 570 (2007) (emphasis added); *Arizona ex rel. Goddard v. Harkins Amusement Enterprises*, No. 08-16075, 2010 U.S. App. Lexis 9042, at *6-7 (9th Cir. Apr. 30, 2010).

[2] *Ashcroft v. Iqbal*, 556 U.S. ___, 129 S.Ct. 1937, 1949 (2009).

[3] *See Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981 (9th Cir. 2009) (affirming Rule 12(b)(6) dismissal in securities fraud case because complaint failed to allege facts showing that defendants intentionally, or with deliberate recklessness, made false or misleading statements).

## II. ARGUMENT

### A. The Claims at Issue Were, As PsychRights Concedes, Covered Under Alaska Medical Assistance Law and, Therefore, Not False or Fraudulent Under the FCA.

PsychRights has failed to state a plausible action for the simple reason that Alaska law and Alaska's Medicaid Plan, which was approved by CMS,[4] unambiguously allow providers to submit Medicaid and CHIP claims to the State for off-label non-compendium uses. Ultimately, whether the State and CMS have correctly interpreted federal law does not matter, because there can be no FCA liability for submitting a Medicaid claim that State law *does* allow.[5]

Although there can be "FCA liability when a 'provider knowingly asks the Government to pay amounts it does not owe,'"[6] there can be no liability here where Alaska *covers* prescribed non-compendium uses of medications. A provider that submits a claim for such a prescription "is merely asking for reimbursement for medication which it has dispensed and for which it is entitled to payment."[7] Such claims do not – indeed, they categorically cannot – involve knowing

[4] The Medicaid program is a joint federal-state public insurance program created by Congress in 1965 to finance the health needs of children from low-income families, single parents with dependent children, and the aged, blind or disabled. *See* Social Security Act Amendments of 1965, Pub. L. No. 89-97, §121, 79 Stat. 343-353 (July 30, 1965). The Medicaid program is administered by each State through a single Medicaid agency, and the federal government participates by providing federal matching grants if certain statutory criteria are satisfied. 42 USC 1396a(a)(5); 42 CFR 431.10. In order to qualify for federal financial participation in a given state's Medicaid program, the State must obtain approval by the Secretary of Health and Human Services of its State Medicaid Plan. *See gen.* 42 U.S.C. § 1396a. By federal law, a State Medicaid Plan must describe the State's administration of the program, eligibility categories, coverage of services, reimbursement methodologies and other aspects of the program. Rules applicable to claim coverage and reimbursement methodologies for any given state's Medicaid program are promulgated by the States, consistent with federal guidelines. 42 U.S.C. 1396a(a)(30); 42 C.F.R. 42 Part 447. Those rules are incorporated at least by reference in its State Medicaid Plan. Federal financial participation in the State's Medicaid program is a match of state expenditures for covered services provided to Medicaid recipients. *See* 42 U.S.C. § 1396b(a). Nowhere does federal Medicaid law forbid the State of Alaska from covering claims for which it does not or will not get federal financial participation.

[5] *United States ex rel Quinn v. Omnicare*, 382 F.3d 432, 441 (3d Cir. 2004). PsychRights does not challenge Defendants' description of the Alaska laws.

[6] *Id*. at 438, *quoting United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (emphasis added).

[7] *Id.*

falsehood or misrepresentation, and therefore no FCA liability can attach to such claims as a matter of law.[8]

Because the Alaska law expressly permits the claims at issue, the Court does not need to reach the parties' argument about the federal law. As shown below, however, the correct interpretation of federal law also establishes that PsychRights cannot plausibly show that any claim was false or fraudulent under the FCA.

### B. Federal Law Also Permits Medicaid Claims for Off-Label Uses Not Supported in the Compendia.

#### 1. The Medicaid "prescribed drugs" benefit is not limited to "covered outpatient drugs."

Opposing Defendants' motion, PsychRights persists in its fundamental error: it wrongly assumes that the Medicaid drug rebate provisions entirely describe and limit the "prescribed drugs" benefit and that states may cover as "prescribed drugs" only those drugs that are "covered outpatient drugs" as defined in the rebate law. Because this error forms the foundation of PsychRights's claims, those claims cannot stand.

"Prescribed drugs" and "covered outpatient drugs" are distinct terms, and no provision of law equates them. In fact, federal Medicaid law allowed states to cover "prescribed drugs" long before the Social Security Act was amended to add the Medicaid drug rebate provisions that include the narrower term "covered outpatient drug."[9] Indeed, the definition of "covered outpatient drugs" in the rebate law makes clear that "covered outpatient drugs" are merely a subset of "prescribed drugs":

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[8] *Id.*

[9] The rebate law was enacted in 1990. States have been allowed to cover "prescribed drugs" since the Medicaid program was first enacted in 1965. Pub.L. 89-97, Title I,§ 121(a), 79 Stat. 379.

> Subject to the exceptions in paragraph (3), the term "covered outpatient drug"means --
>
> > (A) *of those drugs which are treated as prescribed drugs* for purposes of section 1396d(a)(2) of this title, a drug which . . . .[10]

This definition alone is fatal to PsychRights's claim. Different terms must be presumed to mean different things, particularly when they are used in the same sentence.[11] Thus, had Congress intended the rebate law to establish the outer boundaries of the prescribed drugs benefit, it would have done so by defining "prescribed drugs" narrowly, not by introducing a new term. PsychRights's notion that "covered outpatient drugs" narrows "prescribed drugs" for purposes of Medicaid coverage is simply wrong.

Further, Congress knows full well how to prohibit or limit Medicaid coverage and FFP payments.[12] When it does, it makes that intention clear in explicit and often excruciating detail.[13] In the hundreds of pages of Medicaid statutes and the scores of provisions specifying what the federal government will and will not pay for, however, there is not a single statement to the effect that payment "will not be made for any prescribed drug that is not a covered outpatient drug."[14] Given this, it would be error to adopt PsychRights's groundless assumption that

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[10] 42 U.S.C. 1396r-8(k)(2) (emphasis added).

[11] *See, e.g., Russello v. United States*, 464 U.S. 16, 23 (1983) (interpreting RICO statute).

[12] PsychRights mischaracterizes Defendants' position at p. 4 of its opposition. Defendants have not asserted that the Medicaid statutes "allow Medicaid to pay for all prescriptions by a licensed prescriber," and Defendants have never suggested that states enjoy unfettered discretion as to what prescribed drugs to cover. In fact, state discretion is circumscribed by numerous statutory provisions. *E.g.*, 42 U.S.C.A. 1396b(i)(5) and 42 U.S.C.A. 1395y(c); 42 C.F.R. 441.25(a) (proscribing FFP payment for drugs for which FDA approval may be withdrawn); 42 U.S.C. 1396b(i)(10)(B) (proscribing FFP payment for brand-name drugs where generic version could have been dispensed). Defendants' point is instead that such limitations are explicit and should not be implied.

[13] *See, e.g.*, 42 U.S.C.A. 1396b(i) (listing 24 exceptions in 144 lines of text and with at least 25 cross-references to other sections of the Act); 42 U.S.C.A. 1396b(o);42 U.S.C.A. 1396b(r)(1); 42 U.S.C. 1396b(u)(1)(A).

[14] PsychRights points to statutory provisions requiring states to comply with the drug rebate law and imposing numerous rules regarding coverage and payment for covered outpatient drugs, but these deal only with "covered outpatient drugs" and thus miss the point.

Congress's specific provisions governing payment for "covered outpatient drugs" were also meant to limit payment for all "prescribed drugs."

Finally, PsychRights's assumption is directly contrary to CMS's interpretation of the statute. CMS recognizes that "covered outpatient drugs" and "prescribed drugs" are not synonymous, and has reassured State Medicaid Program Directors that the rebate law "made no changes to a State's previous ability to cover" drugs that "do not meet the definition of covered outpatient drug" in the Act, including "experimental" drugs.[15]

**2. The federal drug rebate law recognizes that states may cover non-compendium supported uses.**

As shown above, the rebate statute does not define the Medicaid prescribed drug benefit, as plaintiff contends. But even if it did, the rebate law, through Section 1396r-8(d)(1)(B), recognizes that states may cover prescribed medications for off-label non-compendium uses:

> A State may exclude or otherwise restrict coverage of a covered outpatient drug if – (1) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section).[16]

By allowing states to exclude coverage for drugs prescribed for non-compendium supported uses, the statute obviously contemplates that they also have discretion to cover drugs prescribed for such uses.

PsychRights's contrary interpretation is based solely on its argument that the rebate statute's definition of "covered outpatient drug" in sub-section 1396r-8(k)(3) – "a drug or

[15] Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Release Number 43 (Sept. 8, 1994), Dkt. #91, Ex. 2. Correspondence between CMS and the Utah Attorney General's office, posted on PsychRights's website, confirms that this is still CMS's position. There, a CMS official rejected the very notion advanced by PsychRights, that non-compendium uses are not covered because they fall outside the rebate law's definition of "covered outpatient drug." *Id.*

[16] 42 U.S.C.A. 1396r-8(d)(1)(B).

biological used for a medical indication which is not a medically accepted indication"[17] – renders the provision in sub-section (d)(1)(B) superfluous: that sub-sections (d)(1)(B) and (k)(3) conflict because the former allows states to exclude something that the latter prohibits them from covering in the first place. PsychRights thus urges the Court to give no effect to (d)(1)(B), effectively cutting it out of the statute completely.[18]

There is no such conflict under Defendants' more logical reading of the law. If, as Defendants urge, the rebate law establishes a "floor" on prescribed drug coverage, not a "ceiling," then (d)(1)(B) and (k)(3) are completely harmonious.[19] Both affirm that States may either cover non-compendium uses or exclude them as they see fit. Defendants' interpretation is thus to be preferred under standard canons of statutory construction.[20]

**3. Defendants' interpretation of the federal law is supported by the rebate law's purpose and legislative history.**

Statutes must be interpreted in light of their purpose.[21] The rebate law was expressly intended to ensure that the poor and disabled Americans who rely on Medicaid would have the same access as more wealthy Americans to the medications prescribed by their physicians. It acted to *expand* state Medicaid drug coverage, not restrict it. The Defendants' interpretation of the law is consistent with this purpose. PsychRights's proposed interpretation of the law,

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[17] 42 U.S.C. 1396r-8(k)(3).

[18] Of course, if the two provisions are to be resolved by excising one of them, it would be just as effective to excise the offending language in (k)(3) instead of (d)(1)(B), and PsychRights offers no compelling reason why one should be preferred over the other.

[19] PsychRights quibbles that the rebate law does not really establish a floor because states are not required to offer a prescribed drugs benefit at all. Hair-splitting aside, the parties agree that, although states are not required to offer the benefit, those that do must comply with the rebate statute. Defendants have not suggested otherwise. (*See* Opening Brief at 3.)

[20] *See, e.g.*, *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (noting canon of construction that statutes must be interpreted to give effect to all provisions), *citing Wood v. United States*, 16 Pet. 342, 363 (1842),

[21] *Chevron U.S.A. Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 839 (1984).

however, would improperly subvert Congress's intent by limiting access to prescribed medications for the poor and disabled and by inserting the government into the provider/patient relationship.

The Medicaid rebate law[22] was initially entitled the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990"[23] and the "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990."[24] Both houses of Congress described purposes consistent with these titles. The Senate bill's "findings and purposes" section (Sec. 2) noted market conditions that "limit access to needed medications for poor elderly, minority, and other vulnerable low-income populations who rely on the Medicaid program."[25] A central purpose of the Act, then, was to "enhance physicians' ability to prescribe and the patients' ability to receive needed medications under the Medicaid program."[26] The House sponsors stated the same intent: "This bill we are introducing today assures access to the best prescription drugs on the market for our Nation's poor." [27]

To that end, the rebate law limits how and to what extent states may exclude or restrict prescription drugs from coverage under their state Medicaid plans. Although the states retained the ability to exclude some drugs and to subject others to prior authorization requirements,[28] Congress cautioned that this authority should not be used to interfere in the considered medical judgment of physicians and other authorized prescribers:

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[22] Enacted as Section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508.

[23] H.R. 5589, 101st Cong., 2d Sess.( Ex. 2).

[24] S. 3029, 101st Cong., 2d Sess (Ex. 3).

[25] *Id*., § 2(a)(2).

[26] *Id*., § 2(b)(5).

[27] Hon. Jim Cooper, Extension of Remarks - September 13, 1990 at 2, attached as Ex. 4.

[28] *See* Defs' Memo., Dkt. #91, at 3-4.

> [T]he Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements – i.e., assuring access by Medica[id] beneficiaries to prescription drugs where medically necessary. . . .
>
> The bill would not … alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists.[29]

The legislative history thus demonstrates that the rebate law's purpose was to expand prescribed drug coverage by the States, not restrict it.[30] The law establishes a floor on coverage, not a ceiling.[31] The only interpretation of the statute that is consistent with this explicit intent is the Defendants': that states retain authority to cover non-compendium medical uses in their discretion, as Alaska has chosen to do. PsychRights's proposed interpretation of the statute must be rejected as contrary to Congressional intent.

**4. The district court decisions and Department of Justice litigation statements cited by PsychRights do not support its position.**

Finding no support in the statute or case law for its position, PsychRights resorts to citing statements in a handful of decisions from other federal district courts and Department of Justice press releases, settlement agreements, and litigation statements. However, no court has held, and

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[29] H. Rep. No. 881, 101st Cong., 2d Sess. at 98, reprinted in U.S. Congress and Administrative News at 2110 (Ex. 1).

[30] This is further supported by a story in *The Wall Street Journal* submitted by PsychRights in support of its Refiled Motion for Preliminary Injunction Against Defendants Hogan and Streur, Dkt. No. 113, Ex. 30. At p. 3 of that story, the *Journal* reported that:

> Before 1990, state Medicaid agencies decided on their own whether to cover off-label uses. But after an outcry from cancer and AIDS patients and their doctors that year, lawmakers took control of the process. Following an evaluation by the agency then overseeing Medicaid, Congress barred the states from denying coverage for a drug if the use was approved by the FDA or supported by a citation in one of three drug directories then operating.

[31] Hon. Jim Cooper, Extension of Remarks - September 13, 1990 at 2, attached as Ex. 4.

the DOJ has never asserted, that states are prohibited from covering non-compendium prescriptions. Moreover, these decisions and DOJ statements have no precedential value.

a. The court cases.

The court cases cited by PsychRights do not in fact *hold* that states may not cover non-compendium prescriptions. In each case, the court simply restated the plaintiff's characterization of the law without discussion or analysis, for purposes of ruling on a motion to dismiss.

PsychRights contends that the 2003 *Parke-Davis* opinion cited by Defendants "did not overrule [the court's] previous published opinion where it concluded PsychRights's interpretation is correct."[32] Both the 2001 and 2003 opinions, however, make clear that the court made no such "conclusion" in 2001 because, as the 2003 opinion states, "in the early phases of this litigation, Defendant d[id] not dispute plaintiff's characterization of the law."[33] The other opinions cited by PsychRights are similar. They were rulings on motions to dismiss, and they accepted without discussion the plaintiffs' undisputed characterization of the law.[34]

In fact, the *only* court squarely to have been presented with the statutory interpretation question commented that the debate "may be immaterial," reasoning that, "if the Medicaid statute does *not* give states the discretion to cover off-label, non-compendium prescriptions, but a

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[32] Opp. Br. at 6.

[33] *U.S. ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2, *quoting* 147 F. Supp. 2d at 51.

[34] The language that PsychRights quotes from the *Rost* decision appears in the "Facts" section of the opinion, which the court noted "are taken from the Amended Complaint and treated as undisputed for purposes of this motion." Dkt 108 pp. 6–7. The drug at issue in *Rost*, human growth hormone, was listed in the DRUGDEX compendium. The parties' dispute was whether this listing, and statements in the compendium that the use was "possibly effective," required states to cover the use. *United States ex rel. Rost v. Pfizer*, 253 F.R.D. 11, 12-13 (D. Mass. 2008) (citing Rost's Am. Compl.¶¶ 42, 43). *Rost* also is factually distinct from the present case: the defendant pharmaceutical manufacturer pleaded guilty to marketing human growth hormone, which was FDA approved for three pediatric uses, to an adult population for non-FDA approved uses, such as anti-aging and "body improvements." And in *Ortho-McNeil Pharmaceutical*, the court merely summarized applicable Medicaid and FDA marketing laws in a single short paragraph (saying only that "Medicaid generally reimburses providers only for 'covered outpatient drugs'") before dismissing the complaint for failure to plead fraud with sufficient particularity. *United States v. Ortho-McNeil Pharmaceutical, Inc.*, No. 03-C8239, 2007 WL 2091185 at *2 and *6 (N.D. Ill. 2007).

state misconstrued the statute and authorized coverage of such prescriptions, an FCA action against [defendant] in that state would likely fail, as it would be difficult to establish [defendant's] scienter."[35] Ultimately, the court did not decide the matter, and denied defendants' motion to dismiss because the case involved nationwide conduct and the defendant admitted that at least eight states expressly excluded coverage for non-compendium prescriptions.[36]

b. The DOJ statements and complaints.

The DOJ has never asserted the "*per se*" theory advanced by PsychRights here. As its cited statements make clear, the DOJ's enforcement actions regarding off-label drug sales have all alleged illegal off-label marketing, kickbacks, and other false or deceptive conduct by large pharmaceutical companies. Defendants know of no DOJ action that has been directed at physicians, clinics, pharmacists, or state Medicaid program officials who merely prescribed medications or submitted or processed claims that were authorized under a federally-approved state Medicaid plan.

Further, the DOJ prosecutions and *qui tam* actions cited by PsychRights all involved nationwide or multi-state drug marketing and sales. Although Alaska allows non-compendium prescriptions, several other states have exercised the option to exclude them, and in those states a relator might more credibly argue that a Medicaid claim for such prescriptions could plausibly support an FCA claim.[37] The cited DOJ statements do not assert that all non-compendium prescriptions violate Medicaid laws and constitute false claims, regardless of what the state plans allow, as PsychRights suggests they do. They simply allege that the pharmaceutical companies'

[35] 2003 WL 22048255, at *3.

[36] *Id.*

[37] *See id.* (declining to decide whether states may cover non-compendium uses, because the defendant pharmaceutical company conceded that eight states do not cover such uses).

nationwide or multi-state conduct caused the filing of non-compendium claims that were not authorized under one or more government health programs.[38]

To Defendants' knowledge, the DOJ has never alleged or suggested that claims to a federally-approved state Medicaid program that covers non-compendium uses constitute *per se* false claims.[39] The DOJ's enforcement actions against large pharmaceutical companies are simply not relevant here, and lend no support to PsychRights's position.[40]

## III. CONCLUSION

For the reasons stated above and in Defendants' opening memorandum, the Court should dismiss this case with prejudice, pursuant to Rule 12(b)(6).

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[38] The language that PsychRights highlighted in the Prizer settlement press release simply states that Pfizer had "agreed to . . . resolve *allegations*" under the FCA that it "had illegally promoted four drugs … and caused claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by *those programs.*" Dkt. # 108 Ex. 1. (emphasis added). The statement in *United States v. Gobble* merely states that "Medicaid *ordinarily* does not cover off-label uses that do not qualify as medically accepted indications. *Many state Medicaid programs prohibit covering such uses.*" Dkt. #108 Ex. 2 ¶ 30 (emphasis added). And the settlement agreement in *U.S. v. Astrazeneca,* which also involved claims brought by several state Medicaid programs, alleged only that certain "unapproved" off-label uses of the manufacturer's drugs "were not medically accepted indications for which the United States and the state Medicaid programs provided coverage." Dkt. #108, Ex. 3 at 6.

[39] Indeed, the DOJ was careful to avoid taking any position on this in a Statement of Interest that it filed in *Rost*. *See* Dkt. #113, Ex. 4 at 7 n. 6:

> Notably, this case does not present – at least not at this time – the question this Court left open in Parke-Davis as to whether States have discretion to cover off-label uses that are not supported by a citation in the compendia. *See United States ex rel. Franklin v. Parke-Davis et al.*, 2003 WL 22048255, at *3 (D. Mass. Aug. 22, 2003).

[40] PsychRights does not explain why press releases issued by the DOJ regarding a case settlement, or statements in pleadings that DOJ has filed as a litigant, should be given any consideration (let alone deference) by this Court. They should not be. When DOJ is just a party to litigation, its interpretation of a statute at issue is given no deference. *See Citizens for Responsibility and Ethics in Washington v. U.S. Dept. of Justice*, 658 F. Supp. 2d 217 (D.D.C. 2009) (rejecting the DOJ's interpretation of the FOIA exemptions); *American Civil Liberties Union of N. Cal. v. Dept. of Justice*, No. C 04-4447 PJH, 2005 WL 588354, at *8 (N.D. Cal. March 11, 2005). Courts should, of course, give *Chevron* deference to formal interpretations of an ambiguous statute by the agency charged with administering it. *See Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-45 (1984). But it is CMS, not DOJ, that administers the Medicaid statutes, and it is to CMS that deference is due. *See Alaska D.H.H.S. v. C.M.S.*, 424 F.3d 931, 939-40 (9th Cir. 2005). As shown in Defendants' opening memorandum, CMS has consistently indicated that states may cover non-compendium uses. With all due respect to the DOJ, its litigation positions, settlement agreements, and press releases are owed no deference here.

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CERTIFICATE OF SERVICE

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/s/ Jeffrey M. Feldman
Jeffrey M. Feldman, ABA #7605029
FELDMAN, ORLANSKY & SANDERS

# OMNIBUS BUDGET RECONCILIATION ACT OF 1990

*P.L. 101–508, see page 104 Stat. 1388*

DATES OF CONSIDERATION AND PASSAGE

*House: October 16, 27, 1990 Senate: October 19, 27, 1990*

**House Report (Budget Committee) No. 101–881, Oct. 16, 1990**
**[To accompany H.R. 5835]**

**House Conference Report No. 101–964, Oct. 27, 1990**
**[To accompany H.R. 5835]**

**Cong. Record Vol. 136 (1990)**

*No Senate Report was submitted with this legislation. The House Report (this page) is set out below, the House Conference Report (page 2374) and the President's Signing Statement (page 2930–1) follow.*

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[Including cost estimate of the Congressional Budget Office]

The Committee on the Budget, to whom reconciliation recommendations were submitted pursuant to section 4 of House Concurrent Resolution 310, the concurrent resolution on the budget for fiscal year 1991, having considered the same, report the bill without recommendation.

### STATEMENT OF THE COMMITTEE ON THE BUDGET

The Committee on the Budget to whom reconciliation recommendations were submitted pursuant to section 4 of H. Con. Res. 310, the Concurrent Resolution on the Budget for Fiscal Year 1991, having considered the same, reports a bill embodying those recommendations.

### VOTE OF THE COMMITTEE IN REPORTING THE BILL

In compliance with clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives, the following statement is made relative to the vote of the Committee in reporting the bill. H.R. 5835 was ordered reported by the Committee on October 15, 1990, by voice vote, without recommendations, with a quorum being present.

TITLE IV—COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
*Washington, DC, October 15, 1990.*

Hon. LEON E. PANETTA,
*Chairman, Committee on the Budget,*
*House of Representatives, Washington, D.C. 20515*

DEAR MR. CHAIRMAN: I am transmitting herewith the recommendation of the Committee on Energy and Commerce for changes in laws within its jurisdiction pursuant to section 310 of the Congressional Budget Act of 1974 and section 4(b)(4) of H. Con. Res. 310, the Concurrent Resolution on the Budget-Fiscal Year 1991

The recommendations are embodied in a series of Committee prints adopted by the Committee on October 11, 1990 and reflected in Subtitles A through C of the enclosed statutory language. Also enclosed is accompanying report language and Congressional Budget Office cost estimates.

The enclosed recommendations, when combined with non-duplicative savings achieved in Medicare by the Committee on Ways and Means, and the EPA fees shared with the Committees on Public Works and Agriculture, will meet or exceed budget resolution targets for this Committee.

The Committee has received assurances from the Budget Committee that we will be credited with savings with respect to three provisions which have already been acted on by the House.

First, the automobile fees referenced in Subtitle C of the enclosed legislative language have already been passed in H.R. 3030, the "Clean Air Act Amendments of 1990." Second, radon fees referenced in Subtitle C currently exist as part of the Toxic Substances Control Act. Finally, pursuant to an exchange of letters with the Committee on Government Operations, this Committee's recommendations on Medicaid contained in Subtitle B include the provisions of H.R. 5450, the Computer Matching and Privacy Protection Amendments which passed the House on October 1, 1990.

Thank you for your cooperation in these matters.

Sincerely,

JOHN D. DINGELL,
*Chairman.*

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## PURPOSE AND SUMMARY

The purpose of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1990 is to make revisions in Part B of the Medicare program and in the Medicaid program, in accordance with the reconciliation instructions to the Committee on Energy and Commerce contained in the Concurrent Resolution on the Budget—Fiscal Year 1991. The instructions assume $43.7 billion in savings for the Committee on Energy and Commerce for Fiscal Years 1991-1995 taking into account that other committees which share jurisdiction over Medicare and other programs within the purview of this Committee will contribute to those savings in their reconciliation bills. The instructions further assume new entitlement authority of $2.0 billion over the period FY 1991 through 1995 for purposes of protecting poor and near-poor Medicare beneficiaries from increased cost-sharing obligations under Part B.

The Committee bill consists of three subtitles: subtitle A, relating to Medicare and Regulation of Medicare Supplemental Insurance Policies; subtitle B, relating to Medicaid; and subtitle C, relating to energy and miscellaneous user fees.

Subtitle A consists of 4 Parts. Part 1 contains changes in payments for physician services under Medicare, changes in payments for other covered items and services covered under Medicare. Part 2 contains changes relating to peer review organizations and other provisions, including an extension of the current Medicare secondary payor provisions for the disabled and ESRD beneficiaries. Part 3 includes changes relating to beneficiaries, including increases in the monthly Part B premium and deductible. Part 4 revises standards for Medicare supplemental insurance policies and provides for Federal enforcement of such standards.

Subtitle B, relating to Medicaid, consists of five parts. Part 1 contains provisions that will achieve savings by reforming the purchase of prescription drugs and requiring State Medicaid programs to pay employer group health insurance premiums on behalf of

Medicaid beneficiaries in cases where this would be cost-effective. Part 2 would extend Medicaid payment for Part B premiums for Medicaid beneficiaries with incomes below 125 percent of the Federal poverty line. This initiative is financed by the $2.0 billion assumed in the Budget Resolution for this specific purpose. Part 3 contains provisions to improve the health of low-income children, including phased-in mandatory coverage of children up through age 12 in families with incomes at or below 100 percent of the poverty level. These initiatives are financed on a "pay-as-you-go-basis" by the savings achieved in Part 1, as contemplated by the conferees on the Budget Resolution. Part 4 contains amendments relating to the nursing home reform provisions enacted in the Omnibus Budget Reconciliation Act of 1987. Part 5 contains a number of miscellaneous provisions relating to payments, eligibilty and coverage, health maintenance organizations, demonstration projects and home and community-based waivers, and other issues.

## Background and Need for Legislation

The Concurrent Resolution on the Budget—Fiscal Year 1991 (H.Con.Res. 310, adopted October 9, 1990) provides for unspecified savings in the Medicare program over the period FY 1991 through FY 1995. The Budget Resolution assigns this savings target to both this Committee and the Committee on Ways and Means, without instructions as to how much is to be achieved in Part A, which is not within the jurisdiction of this Committee, and how much is to be achieved in Part B, which is within the jurisdiction of both committees. Therefore, this Committee does not have a specific target for the Medicare savings it must achieve. The net savings from this Committee are consolidated with the net savings from the Committee on Ways and Means to determine whether the target has been met. The Committee is concerned that the increases in Part B premiums and deductibles assumpted by the Budget Resolution and contained in this bill will impose a disproportionately heavy financial burden on low-income Medicare beneficiaries. Accordingly, the Committee bill includes a provision to pay the Part B premiums of beneficiaries with income below 125 percent of the Federal poverty level and liquid assets of $4,000 or less. The Committee also remains concerned that continual reductions in payments to providers of service, without adequate evaluation of the effects of prior reductions, may impact on enrollees in the form of reduced quality of care or barriers to accessibility.

The Budget Resolution also apparently assumes reductions of $2.38 billion in Medicaid outlays over the period FY 1991 through 1995. The Committee bill would achieve these savings primarily by reforming the purchase of prescription drugs by the States and by requiring the States, where cost-effective, to purchase employer group health coverage on behalf of Medicaid beneficiaries. The savings achieved under the Committee's recommendations would exceed the Budget Resolution's apparent target by approximately several hundred million dollars over the next five years. In an effort to respond to the health care crisis confronting poor children, the Committee is recommending that these savings be applied to initiatives to improve child health. Foremost among these is a

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modest, incremental expansion in Medicaid coverage for children through age 12 in families with incomes at or below 100 percent of the Federal poverty level. This will result in the extension of basic health care coverage to an estimated 700,000 children in 1995 when the provision is fully implemented.

### HEARINGS

The Subcommittee on Health and the Environment held one day of hearings on Medicare Program Outlay Reductions on June 27, 1990, and heard testimony from 10 witnesses, including the Physician Payment Review Commission, representatives of 6 medical associations, and 3 other organizations. On June 7, 1990, the Subcommittee on Health and the Environment held joint hearings with the Subcommittee on Commerce, Consumer Protection, and Competitiveness on reform of the Medicare Supplemental Insurance Market. Testimony was received from 10 witnesses, including 2 Members of Congress, the General Accounting Office, representatives of the health insurance industry, and 3 other organizations. The Subcommittee on Health and the Environment held field hearings on March 5, 1990, in Atlanta, Georgia, on Medicare Part B Carrier Issues. Testimony was received from 10 witnesses, including 4 Members of Congress, regional offices of the Health Care Financing Administration and HHS Inspector General, and representatives of 4 other groups.

The Subcommittee held two days of hearings on Medicaid Budget Initiatives on September 10, 1990, and September 14, 1990, and heard testimony from 37 witnesses, including nine Members of Congress, the General Accounting Office, HHS Office of the Inspector General, and the Health Care Financing Adminisration. Illinois, on Medicaid and the Maternal and Child Health Block Grants on March 5, 1990. Testimony was received from 11 witnesses, including the Illinois Department of Public Health, and the Illinois Department of Public Aid, and representatives of various area health care providers.

### COMMITTEE CONSIDERATION

On October 11, 1990, the Committee met in an open mark-up session and orderd the Committee Print, as amended, transmitted to the Budget Committee by a voice vote, a quorum being present.

### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, no oversight findings or recommendations have been made to the Committee.

### COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

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COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that the bill will reduce Medicare program outlays by $1.7 billion in FY 1991 and $24.4 billion over the period FY 1991 through 1995, and will reduce Medicaid program outlays by $337 million over the period FY 1991 through 1995.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
*Washington, DC, October 15, 1990.*

Hon. JOHN D. DINGELL,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for the Reconciliation recommendations of the Committee on Energy and Commerce, as ordered transmitted to the House Committee on the Budget, October 15, 1990.

The estimates included in the attached table represent the 1991-1995 effects on the federal budget and on the budget resolution baseline of the Committee's legislative proposals affecting spending. CBO understands that the Committee on the Budget will be responsible for interpreting how savings contained in these legislative proposals measure against the budget resolution reconciliation instructions.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

ROBERT D. REISCHAUER,
*Director.*

ENERGY AND COMMERCE: RECONCILIATION PROVISIONS

[By fiscal year, in millions of dollars]

| | 1991 | 1992 | 1993 | 1994 | 1995 | Total 1991-95 |
|---|---|---|---|---|---|---|
| SUBTITLE A—PROVISIONS RELATING TO THE MEDICARE PROGRAM | | | | | | |
| Part 1—Provisions Relating to Part B | | | | | | |
| 4001 Payments for Overvalued Procedures | −115 | −190 | −210 | −235 | −260 | −1010 |
| 4002 Payments for radiology services | −87 | −153 | −176 | −194 | −229 | −837 |
| 4003 Payments for anesthesia services | −35 | −50 | −55 | −60 | −65 | −265 |
| 4004 Payments for pathology services | −10 | −10 | −15 | −15 | −15 | −65 |
| 4005 Payments for certain other physician services | −95 | −155 | −175 | −190 | −215 | −830 |
| 4006 Update for physicians services | −195 | −390 | −475 | −525 | −590 | −2,175 |
| 4007 Charges of new physicians and practitioners | −55 | −105 | −125 | −140 | −155 | −580 |
| 4008 Payment for technical components of diagnostic tests | −20 | −35 | −35 | −40 | −45 | −175 |
| 4009 Reciprocal billing arrangements for physicians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4010 Aggregation rule for claims for similar physicians' services | 0 | 0 | 0 | 0 | 0 | 0 |
| 4011 Practicing physicians advisory council [1] | 0 | 0 | 0 | 0 | 0 | 0 |
| 4012 Release of medical review screens | 0 | 0 | 0 | 0 | 0 | 0 |
| 4013 Technical corrections relating to physician payment | 0 | 0 | 0 | 0 | 0 | 0 |
| 4021 Payments for hospital outpatient services: | | | | | | |
| a. Outpatient capital | −65 | −90 | −85 | −90 | −80 | −410 |
| b. Outpatient services | −115 | −150 | −180 | −210 | −245 | −900 |

# LEGISLATIVE HISTORY
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ENERGY AND COMMERCE: RECONCILIATION PROVISIONS—Continued

[By fiscal year, in millions of dollars]

| | 1991 | 1992 | 1993 | 1994 | 1995 | Total 1991-95 |
|---|---|---|---|---|---|---|
| 4022 Payments for durable medical equipment | −170 | −305 | −380 | −445 | −490 | −1,790 |
| 4023 Payment for clinical laboratory services | −95 | −155 | −175 | −200 | −225 | −850 |
| 4024 Coverage of nurse practitioner in rural areas | 3 | 4 | 5 | 5 | 6 | 23 |
| 4025 Clarifying coverage of eyeglasses following cataract surgery | −30 | −45 | −50 | −50 | −55 | −230 |
| 4026 Coverage of injectible drugs for osteoporosis | 1 | 1 | 0 | 0 | 0 | 2 |
| 4027 Conditions of cataract surgery alternatives demonstration | 0 | 0 | 0 | 0 | 0 | 0 |
| 4031 Medicare carrier notice to State medical boards | 0 | 0 | 0 | 0 | 0 | 0 |
| 4032 Technical and miscellaneous corrections to part B | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal | −1,083 | −1,828 | −2,129 | −2,389 | −2,663 | −10,092 |
| Part 2—Provisions Relating to Parts A & B | | | | | | |
| 4101 PRO coordination with carriers | 0 | 0 | 0 | 0 | 0 | 0 |
| 4102 Confidentiality of peer review deliberations | 0 | 0 | 0 | 0 | 0 | 0 |
| 4103 Role of peer review in hospital transfers | 0 | 0 | 0 | 0 | 0 | 0 |
| 4104 Peer review notice | 0 | 0 | 0 | 0 | 0 | 0 |
| 4105 Notice to State medical boards of adverse actions | 0 | 0 | 0 | 0 | 0 | 0 |
| 4106 Carrier notice to State medical boards | 0 | 0 | 0 | 0 | 0 | 0 |
| 4121 Extension of medicare secondary payor provisions: | | | | | | |
| a. ESRD to 18 months | −50 | −55 | −60 | −65 | −65 | −295 |
| b. Extension of disabled secondary payer provisions | 0 | −570 | −780 | −800 | −830 | −2,980 |
| 4122 Provisions relating to HMO's | (2) | (2) | (2) | (2) | (2) | (2) |
| 4123 Demonstration project for staff-assisted home dialysis | 1 | 1 | 0 | 0 | 0 | 2 |
| 4124 Extension of reporting deadline for Alzheimer's disease demonstration project | 0 | 0 | 0 | 0 | 0 | 0 |
| 4125 Miscellaneous technical corrections | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal | −49 | −624 | −840 | −865 | −895 | −3,273 |
| Part 3—Provisions Relating to Beneficiaries | | | | | | |
| 4201 Part B premium [3] | −275 | −370 | −1,320 | −2,590 | −3,965 | −8,520 |
| 4202 Change in part B deductible | −350 | −550 | −560 | −570 | −580 | −2,610 |
| Subtotal | −625 | −920 | −1,880 | −3,160 | −4,545 | −11,130 |
| Part 4—Standards for Medicare Supplemental Insurance Policies | | | | | | |
| 4301 Simplification of Medicare supplemental policies [1] | 0 | 0 | 0 | 0 | 0 | 0 |
| 4302 Requiring approval of State for sale in the State | 0 | 0 | 0 | 0 | 0 | 0 |
| 4303 Preventing duplication | 0 | 0 | 0 | 0 | 0 | 0 |
| 4304 Loss ratios [1] | 0 | 0 | 0 | 0 | 0 | 0 |
| 4305 Limitation on certain sales commissions | 0 | 0 | 0 | 0 | 0 | 0 |
| 4306 Clarification of treatment of plans offered by health maintenance organizations | 0 | 0 | 0 | 0 | 0 | 0 |
| 4307 Prohibition of certain discriminatory practices | 0 | 0 | 0 | 0 | 0 | 0 |
| 4308 Health insurance advisory service for medicare beneficiaries | 0 | 0 | 0 | 0 | 0 | 0 |
| 4309 Additional enforcement through Public Health Service Act | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal | 0 | 0 | 0 | 0 | 0 | 0 |
| Medicare subtotal | −1,737 | −3,372 | −4,849 | −6,414 | −8,103 | −24,495 |
| Subtitle B—Medicaid Program | | | | | | |
| Part 1—Reductions in Spending | | | | | | |
| 4401 Reimbursement for prescribed drugs | −100 | −250 | −445 | −570 | −740 | −2,105 |

## ENERGY AND COMMERCE: RECONCILIATION PROVISIONS—Continued

[By fiscal year, in millions of dollars]

| | 1991 | 1992 | 1993 | 1994 | 1995 | Total 1991–95 |
|---|---|---|---|---|---|---|
| 4402 Requiring Medicaid payment of premiums and cost-sharing for enrollment under group health plan where cost effective | −85 | −160 | −205 | −250 | −305 | −1,005 |
| 4403 Computer matching and privacy protection amendments | 0 | −15 | −35 | −40 | −45 | −135 |
| Part 2—Protection of Low-Income Medicare Beneficiaries | | | | | | |
| 4411 Medicaid payment for premiums for Medicare beneficiaries with incomes below 125 percent of poverty | 200 | 285 | 360 | 470 | 595 | 1,910 |
| Part 3—Improvements in Child Health | | | | | | |
| 4421 Phased-in mandatory coverage of children up to 100 percent of poverty | 10 | 55 | 105 | 160 | 230 | 560 |
| 4422 Mandatory continuation of benefits for pregnant women through post-partum and certain infants throughout first year of life | 15 | 30 | 35 | 35 | 40 | 155 |
| 4423 Mandatory use of Outreach locations other than welfare offices | 9 | 50 | 55 | 55 | 60 | 229 |
| 4424 Presumptive eligibility | 1 | 1 | 2 | 2 | 2 | 8 |
| 4425 Role in paternity determinations | (2) | (2) | (2) | (2) | (2) | (2) |
| 4426 Report and transition on errors in eligibility determinations | (2) | (2) | 0 | 0 | 0 | 0 |
| Part 4—Nursing home reform provisions | | | | | | |
| 4431 Medicaid nursing home reform | −1 | −2 | −2 | −2 | −3 | −10 |
| Part 5—Miscellaneous provisions | | | | | | |
| 4441 State Medicaid matching payments through voluntary contributions and State taxes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4442 Disproportionate share hospitals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4443 Alternate State payment adjustments to disproportionate share hospitals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4444 Minimum payment adjustment for certain disproportionate share hospitals in Illinois | 10 | 10 | 10 | 0 | 0 | 30 |
| 4445 Federally qualified health centers | 3 | 4 | 4 | 4 | 4 | 15 |
| 4446 Hospice payments | 0 | 0 | 0 | 0 | 0 | 0 |
| 4447 Limitations on disallowance of certain inpatient psychiatric hospital services | 0 | 0 | 0 | 0 | 0 | 0 |
| 4448 Treatment of interest on Indiana disallowance | 0 | 0 | 0 | 0 | 0 | 0 |
| 4451 Optional payment of premiums for "COBRA" continuation coverage where cost effective | 0 | 0 | 0 | 0 | 0 | 0 |
| 4452 Provisions relating to spousal impoverishment | 0 | 0 | 0 | 0 | 0 | 0 |
| 4453 Disregarding German reparation payments from post-eligibility treatment of income under the Medicaid Program | (2) | 1 | 1 | 1 | 1 | 4 |
| 4454 Amendments relating to Medicaid transition provision | 0 | 0 | 0 | 0 | 0 | 0 |
| 4455 Clarifying effect of hospice election | 0 | 0 | 0 | 0 | 0 | 0 |
| 4456 Clarification of application of 133 percent income limit to medically needy | 0 | 0 | 0 | 0 | 0 | 0 |
| 4457 Codification of coverage of rehabilitation services | 0 | 0 | 0 | 0 | 0 | 0 |
| 4458 Personal care services in Minnesota | 1 | 1 | 1 | 1 | 1 | 5 |
| 4461 Requirements for health maintenance organizations | 0 | 0 | 0 | 0 | 0 | 0 |
| 4462 Health maintenance organization special rules | 0 | 0 | 0 | 0 | 0 | 0 |
| 4463 Extension and expansion of Minnesota prepaid demonstration | 0 | 0 | 0 | 0 | 0 | 0 |
| 4464 Treatment of Dayton area health plan | −2 | −2 | −2 | −2 | −2 | −10 |
| 4465 Treatment of certain county-operated health insuring organizations | 0 | 0 | 0 | 0 | 0 | 0 |
| 4471 Waiver authority for demonstrations to protect assets through private long-term care insurance | 0 | 0 | 0 | 0 | 0 | 0 |
| 4472 Timely payment under waivers of freedom of choice of hospital services | 0 | 0 | 0 | 0 | 0 | 0 |

ENERGY AND COMMERCE: RECONCILIATION PROVISIONS—Continued

[By fiscal year, in millions of dollars]

| | 1991 | 1992 | 1993 | 1994 | 1995 | Total 1991–95 |
|---|---|---|---|---|---|---|
| 4473 Home and community-based services waivers: | | | | | | |
| (1) Clarify definition of room and board | 0 | 0 | 0 | 0 | 0 | 0 |
| (2) Treatment of persons with mental retardation or a related condition in a decertified facility | 0 | 0 | 0 | 0 | 0 | 0 |
| (3) Scope of respite care | 0 | 0 | 0 | 0 | 0 | 0 |
| (4) Permitting adjustment in estimates to take into account preadmission screening requirement | 0 | 0 | 0 | 0 | 0 | 0 |
| 4474 Provisions relating to frail elderly demonstration project waivers: | | | | | | |
| (a) Expansion of waivers | (2) | (2) | (2) | (2) | (2) | (2) |
| (b) Application of special improvement rules | (2) | (2) | (2) | (2) | (2) | (2) |
| 4481 Right to self-determination with respect to health care | (2) | 1 | 1 | 1 | 1 | 4 |
| 4482 Provisions relating to quality of physician services | (2) | 1 | 1 | 1 | 1 | 4 |
| 4483 Clarification of authority of inspector general | 0 | 0 | 0 | 0 | 0 | 0 |
| 4484 Notice to State medical boards when adverse actions taken | 0 | 0 | 0 | 0 | 0 | 0 |
| 4485 Miscellaneous provisions | (2) | (2) | (2) | 0 | 0 | (2) |
| Medicaid Subtotal | 61 | 10 | −114 | −134 | −160 | −337 |
| SUBTITLE C—OTHER PROVISIONS | | | | | | |
| 4502 NRC fees (offsetting receipts) | −287 | −298 | −310 | −323 | −336 | −1,554 |
| 4511 Railroad safety user fees (offsetting receipts) | −20 | −35 | −36 | −38 | −40 | −169 |
| 4521 U.S. travel and tourism user fees (offseting receipts) | −10 | −19 | −18 | −20 | −18 | −85 |
| 4531 EPA user fees (offsetting receipts) | −4 | −5 | −5 | −5 | −5 | −24 |
| Other total direct spending effects | −321 | −357 | −369 | −386 | −399 | −1,832 |
| Direct spending total | −2,017 | −3,719 | −5,332 | −6,934 | −8,662 | −26,664 |
| State and local effects | −85 | −180 | −275 | −295 | −325 | −1,160 |

[1] No direct spending would result from this provision, but a small amount (less than $500,000) would be required from funds subject to Appropriation Committee action.
[2] Cost or saving estimated at less than $500,000.
[3] Part B monthly premium amounts: 1991, $30.90; 1992, $32.20; 1993, $37.00; 1994, $41.70; 1995, $44.70.

## Inflationary Impact Statement

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee states that the reported bill will reduce inflation by reducing Medicare and Medicaid program outlays by over $27 billion over the next 5 years.

## Section-by-Section Analysis

### PART 1—PROVISIONS RELATING TO PART B

### *Subpart A—Payment for Physicians' Services*

*Section 4001—Certain overvalued procedures*

The Omnibus Budget Reconciliation Act of 1989 provided for reductions in the prevailing charges for a list of 244 procedures identified as overvalued in relation to the amounts estimated for such procedures under the Medicare Fee Schedule beginning in 1992. The Physician Payment Review Commission (PhysPRC) recommended these specific procedures for reductions because the national average prevailing charges for these procedures exceeded the estimated fee schedule amounts by at least 10 percent.

from 60% to 70%. Dread disease and indemnity policies are required to meet a loss ratio requirement of 60%.

The bill would also require insurers to provide States with more detailed information on loss ratios, expand access to such information, and direct GAO to conduct regular audits on insurer compliance with loss ratio requirements. It also would require credits to policyholders on a proportional basis in amounts necessary to bring the policy within the applicable loss ratio standard. Civil penalties of not more than $25,000 for each violation of loss ratio requirements would be established.

DISCRIMINATORY PRACTICES

The bill would require insurers to offer persons reaching age 65 the opportunity, for a 6-month period, to purchase a Medigap policy without conditioning the issuance of the policy, on the health status of such persons and at a level premium. It would establish civil penalties for violations. The bill would also provide that replacement policies (for policies in effect for 6 months or longer) may not contain any new, pre-existing conditions, waiting period, elimination periods or probationary periods.

MISCELLANEOUS

The bill would prohibit first-year sales commissions in excess of 200% of renewal commissions and establish civil and criminal penalties for violations.

It also would strengthen the requirement that all Medigap policies be approved by the State in which they are sold.

It would direct the Secretary of HHS to establish a health insurance advisory service program for Medicare beneficiaries and require such program to provide information, counseling and assistance regarding Medicare, Medicaid, and Medigap policies.

Finally, the bill would require insurers seeking premium increases in Medigap policies to submit certain information to States in advance, including actuarial certification of loss ratio compliance.

*Subtitle B—Medicaid Program*

PART 1—REDUCTIONS IN SPENDING

*Sec. 4401—Reimbursement for prescribed drugs*

Under current law, States may, at their option, offer coverage for prescribed drugs. In order to qualify for Federal matching funds, drug products must be (1) prescribed by a physician or other licensed practitioner, (2) dispensed by licensed pharmacists and licensed authorized practitioners, and (3) dispensed on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records. Federal matching funds are not available for any drugs which the Secretary has determined is less than effective. States may limit the number or prescription drugs which they cover through a formulatory. They may also require prior authorization with respect to any of the prescription drugs which they elect to cover.

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Medicaid regulations establish aggregate limits on payments for prescription drugs. Two separate limits are used: one for multiple source drugs for which therapeutic equivalents or "generic" versions are available from more than one manufacturer, and one for all other drugs. With respect to each multiple source drug, the Health Care Financing Administration (HCFA) establishes a price limit equal to 150 percent of the estimated wholesale cost of the least expensive therapeutic equivalent. The State's total payments for all such drugs during a given period may not exceed what would have been spent if the State had paid the price limits plus a reasonable dispensing fee. The State may pay more for any particular drug so long as the total for all drugs does not exceed the aggregate limit. If the prescribing physician specifies that generic substitution is unacceptable (for example, by writing "dispense as written" or "no substitution" on the prescription), the HCFA price limits do not apply. The pharmacy must supply the brand-name drug and may be paid the full brand-name cost.

With respect to all other drugs (including multiple source drugs for which the prescribing physician has requested no substitution), aggregage statewide payments may not exceed the lesser of (a) the pharmacies' usual and customary charge to the general public and (b) the estimated acquisition (wholesale) cost of ingredients plus a reasonable dispensing fee. For most drugs, the ingredient cost is limited to the State's best estimate of what providers generally are paying for a drug.

The Budget Summit agreement dated September 30, 1990, assumed savings from the Medicaid program from reductions in payments for brand-name drugs. Specifically, the Summit agreement assumed that for single source drugs manufacturers would be limited to charging Medicaid the best price given any bulk purchaser, subject to a minimum discount of 10 percent, with savings returned to Medicaid through a quarterly rebate. On September 14, 1990, the Subcommittee on Health and the Environment heard testimony that Medicaid pays substantially more for many single-source drugs than do other large purchasers. In California, the Medi-Cal program pays $149.08 for 100 250 mg. tablets of Ceclor, used to treat certain types of respiratory infections; the Department of Veterans Affairs pays $58.77, a discount of 61 percent. Similarly, in the case of Tagamet, used to treat ulcers, the Medi-Cal program pays $54.77 for 100 tablets (300 mg.), while the DVA pays $27.65, or 49 percent less. Senator David Pryor, Chairman of the Senate Special Committee on Aging testified that large private sector purchasers, including HMOs and hospital group purchasing organizations, also receive substantial discounts.

In fiscal year 1991, Federal Medicaid payments for prescription drugs are projected by HCFA to reach $2.8 billion. The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range

of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

Specifically, the Committee bill would deny Federal Medicaid matching payments for the covered outpatient drugs of any manufacturer that does not enter into an agreement with the Secretary to provide specified rebates with respect to all of the manufacturer's drugs to all States on a quarterly basis. A covered outpatient drug includes all prescription drugs except those for which Medicaid payments is made as part of payment for the following services: inpatient hospital, hospice, dental, physician office visits, outpatient hospital emergency room visits, and outpatient surgical procedures.

With respect to single source drugs and innovator multiple source drugs, the amount of the rebate owed to each State would be equal to the product of (1) the difference between the average manufacturer price to wholesalers for the drug and the manufacturer's best price, and (2) the number of units dispensed. The manufacturer's best price would be the lower of (1) the lowest price available to any wholesaler, retailer, provider, nonprofit entity, or governmental entity during the quarter, or (2) the lowest price in effect on September 1, 1990, increased by the percentage increase in the consumer price index for all urban consumers. The lowest price would include cash discounts, free goods, volume discounts, and rebates, and would be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package. Prices considered by the Secretary to be merely nominal would not be included in determining lowest price. The minimum rebate with respect to single source and innovator multiple source drugs would be 10 percent of the average manufacturer's price times the number of unit prescribed. The maximum rebate would be 25 percent for the period April 1, 1991, through March 30, 1993, and 50 percent for the period April 1, 1993, through March 30, 1995. Thereafter, the rebate owed would not be subject to a maximum limit.

With respect to all covered outpatient drugs other than single source and innovator multiple source drugs, the amount of the rebate would be equal to the product of (1) 10 percent of the average manufacturer price to wholesalers during the quarter (after deducting customary prompt payment discounts) and (2) the number of units dispensed during the quarter.

Rebates would be due to each State within 30 days after the receipt by the manufacturer of information from the State regarding the total number of units of each dosage form and strength of each of the manufacturer's drugs dispensed during the quarter. In order to enable to Secretary to verify accuracy of the rebates paid, each manufacturer entering into an agreement with the Secretary would be required to report to the Secretary, on a quarterly basis, the average manufacturer price for all of its covered drugs and, with respect to single source and innovator multiple source drugs, the manufacturer's best price. The Secretary would be authorized to survey wholesalers and manufacturers that directly distribute their covered drugs to verify average manufacturer prices. Infor-

mation disclosed by manufacturers or wholesalers regarding average manufacturer price or best price would be confidential and could be disclosed only as the Secretary determines necessary to carry out this provision and to permit review by the Comptroller General or Inspector General.

The prohibition against Federal matching payments for any prescription drug sold by a manufacturer without an agreement would take effect for drugs dispensed on or after February 1, 1991, except that any agreement entered into with the Secretary before that date would be effective with respect to drugs dispensed on or after January 1, 1991.

States that elect to offer prescription drug coverage under their Medicaid programs would be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement with the Secretary. This requirement would take effect April 1, 1991. As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., assuring access by Medical beneficiaries to prescription drugs where medically necessary.

Effective January 1, 1993, States would be required to establish a drug use review program for covered outpatient drugs in order to assure that prescriptions written for Medicaid beneficiaries are appropriate and medically necessary. In making these determinations, State would be required to use any applicable guidelines developed by the Agency for Health Care Policy and Research. Each State's drug use review program would have to include both prospective and retrospective drug review. Prospective drug review would involve the review of drug therapy before a prescription is filled or delivered, typically at the point-of-sale or point-of-distribution. Retrospective drug use review would involve the period examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse or underuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs.

The Committee emphasizes that the bill is framed to achieve significant Medicaid savings with the minimum possible amount of disruption of current program arrangements. The bill would not require therapeutic substitution or in any other way alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists. It would not alter the relationship between physicians and pharmacists. Nor would it alter the current payment arrangements between State Medicaid programs and pharmacists. Finally, the bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs.

HR 5589 IH

101st CONGRESS

2d Session

**H. R. 5589**

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

**IN THE HOUSE OF REPRESENTATIVES**

**September 12, 1990**

Mr. WYDEN (for himself and Mr. COOPER) introduced the following bill; which was referred to the Committee on Energy and Commerce

**A BILL**

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

## SECTION 1. SHORT TITLE.

This Act may be cited as the `Medicaid Prescription Drug Fair Access and Pricing Act of 1990'.

## SEC. 2. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) IN GENERAL-

(1) DENIAL OF FEDERAL FINANCIAL PARTICIPATION UNLESS REBATE AGREEMENTS AND DRUG USE REVIEW IN EFFECT- Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended--

(A) by striking the period at the end of paragraph (9) and inserting `; or', and

(B) by inserting after paragraph (9) the following new paragraph:

`(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless, except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927 (a) with respect to the drugs so dispensed in all States.'.

(2) PROHIBITING STATE PLAN DRUG ACCESS LIMITATIONS FOR DRUGS COVERED UNDER A REBATE AGREEMENT- Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended--

(A) by striking `and' at the end of paragraph (52),

(B) by striking the period at the end of paragraph (53) and inserting `; and', and

(C) by inserting after paragraph (53) the following new paragraph:

`(54)(A) provide that, in the case of a manufacturer which has entered into and complies with an agreement under section 1927(a), any formulary or similar restriction (other than a prior authorization program described in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of the manufacturer which are prescribed (on or after April 1, 1991) for a medically accepted indication (as defined in section 1927(g) (6)),

`(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of section 1927(d), and

`(C) effective January 1, 1993, provide for drug use review in accordance with section 1927(e). '.

(3) REBATE AGREEMENTS FOR COVERED OUTPATIENT DRUGS, DRUG USE REVIEW, AND RELATED PROVISIONS- Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section:

## `PAYMENT FOR PRESCRIBED DRUGS

`SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT-

`(1) IN GENERAL- In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of all the States. If a manufacturer has not entered into such an agreement before February 1, 1991, such an agreement, subsequently entered into,

shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

`(2) EFFECTIVE DATE- Paragraph (1) shall first apply to drugs dispensed under this title on or after April 1, 1991.

`(3) AUTHORIZING PAYMENT, WITH PRIOR AUTHORIZATION, FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS- Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if the physician has obtained approval of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d).

`(4) EFFECT ON EXISTING AGREEMENTS- In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement may remain in effect, and shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State establishes to the satisfaction of the Secretary that the agreement provides for rebates that are at least as large as the rebates otherwise required under this section.

`(b) TERMS OF REBATE AGREEMENT-

`(1) QUARTERLY REBATES-

`(A) IN GENERAL- A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, for a rebate each calendar quarter in the amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter. Such a rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for that quarter.

`(B) OFFSET AGAINST MEDICAL ASSISTANCE- Amounts received by a State as rebates under this section in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

`(2) STATE PROVISION OF INFORMATION-

`(A) STATE RESPONSIBILITY- Each State agency under this title shall report to each manufacturer, not later than 60 days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient

drug dispensed under the plan during the quarter, and shall promptly transmit a copy of such report to the Secretary.

`(B) LIMITATIONS ON AUDIT- A manufacturer has the right to an audit only of the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

`(C) NOTICE TO SECRETARY- Each State agency shall notify the Secretary within 30 days after the date each rebate is received under this section.

`(3) MANUFACTURER PROVISION OF PRICE INFORMATION-

`(A) IN GENERAL- Each manufacturer with an agreement in effect under this section shall report to the Secretary (and make available upon request to each State agency)--

`(i) not later than 30 days after the last day of each quarter (beginning on or after April 1, 1991), on the average manufacturer price (as defined in subsection (g)(1)) and (for single source drugs and innovator multiple source drugs) the manufacturer's best price (as defined in subsection (c)(3)(A)) for covered outpatient drugs for the quarter, and

`(ii) not later than 30 days after the date of entering into an agreement under this section on the best price (as defined in subsection (c)(3)(B)) as of September 1, 1990 for each of the manufacturer's covered outpatient drugs.

`(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE - The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary to verify average manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $10,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(C) PENALTIES-

`(i) FAILURE TO PROVIDE TIMELY INFORMATION- In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the rebate required under the agreement shall be increased by $10,000 for each day in which such information has not been provided, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

`(ii) FALSE INFORMATION- Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law (including exclusion under section 1128(b)(11)). The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(D) CONFIDENTIALITY OF INFORMATION- Information disclosed by manufacturers or wholesalers under this paragraph is confidential and shall not be disclosed by the Secretary or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General and the Inspector General of the Department to review the information provided.

`(4) LENGTH OF AGREEMENT-

`(A) IN GENERAL- A rebate agreement shall be effective for an initial period of 1 year and shall be automatically renewed for an additional 1-year period unless terminated under subparagraph (B).

`(B) TERMINATION-

`(i) BY THE SECRETARY- The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing

concerning such a termination, but such hearing shall not delay the effective date of the termination.

`(ii) BY A MANUFACTURER- A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until such period (of not more than 1 year) after the date of the notice as the Secretary may provide by regulation.

`(iii) EFFECTIVENESS OF TERMINATION- Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

`(C) DELAY BEFORE REENTRY- In the case of any rebate agreement with a manufacturer under this section which is terminated, a new such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 year has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

`(c) AMOUNT OF REBATE-

`(1) IN GENERAL-

`(A) SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- Except as provided in this subsection and subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to single source drugs and innovator multiple source drugs shall be equal to the product of--

`(i) the amount by which (I) the average manufacturer price to wholesalers during the quarter for each dosage form and strength of a covered outpatient drug, exceeds (II) the manufacturer's best price (as defined in paragraph (3)) for such form and strength; and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2)).

`(B) OTHER DRUGS- Except as provided in subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

`(i) 10 percent of the average manufacturer price to wholesalers during the quarter for each dosage form and strength of a covered outpatient drug (after deducting customary prompt payment discounts); and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2).

`(2) MINIMUM AND MAXIMUM REBATE RATES FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- In no case shall the amount of the rebate described in paragraph (1)(A) for a manufacturer for a calendar quarter with respect to single source drugs and innovator multiple source drugs--

`(A) be less than 10 percent, or

`(B) for calendar quarters beginning before April 1, 1995, be more than--

`(i) 25 percent (for each quarter during the 8-calendar-quarter period beginning April 1, 1991), or

`(ii)) 50 percent (for each quarter during the 8-calendar-quarter period beginning April 1, 1993),

of the product of the price described in paragraph (1)(A)(i)(I) and the number of units described in paragraph (1)(A)(ii) for the quarter.

`(3) BEST PRICE DEFINED-

`(A) IN GENERAL- In this subsection, the term `best price' means, for a covered outpatient drug of a manufacturer dispensed in a calendar quarter--

`(i) the lowest price available for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States during the quarter, or

`(ii) the lowest price in effect for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States in effect on September 1, 1990, increased (for calendar quarters beginning on or after January 1, 1991) by the percentage increase in the Consumer Price Index for All Urban Consumers

(all items; U.S. city average) from September 1990 to the month before the beginning of the calendar quarter involved,

whichever is lower.

`(B) TREATMENT OF NEW DRUGS- In the case of a covered outpatient drug approved for marketing after September 1, 1990, any reference in subparagraph (A)(ii) to `September 1, 1990' or `September 1990' shall be a reference to the first day of the first month, and the first month, respectively, during which the drug was marketed and any reference in subsection (b)(3)(A)(ii) to `30 days after the date of entering into an agreement under this section on the best price described in paragraph (3)(B) as of September 1, 1990' shall be a reference to `30 days after the date the drug is first marketed in the United States'.

`(C) COMPUTATION OF LOWEST PRICE- The lowest price described in this paragraph shall be inclusive of cash discounts, free goods, volume discounts, and rebates, shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount.

`(d) LIMITATIONS ON PRIOR AUTHORIZATION PROGRAMS-

`(1) CONDITIONS- A State plan under this title may not require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (g)(6)) unless the system providing for such approval--

`(A) is available to physicians 24 hours a day, 7 days a week, and

`(B) provides an immediate response by telephone or other telecommunication device to an inquiry.

`(2) DELAYED EFFECTIVE DATE- Paragraph (1) shall only apply to prior authorization programs for drugs dispensed on or after April 1, 1991.

`(e) DRUG USE REVIEW-

`(1) IN GENERAL- In order to meet the requirement of section 1902(a)(54)(C), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs (other than psychopharmacologic drugs described in section 1919(c)(2)(D) dispensed to residents of nursing facilities) in order to assure, in accordance with any guidelines developed by the

Agency for Health Care Policy and Research, that prescriptions (A) are appropriate, (B) are medically necessary, and (C) are not likely to result in adverse medical results.

`(2) DESCRIPTION OF PROGRAM- Each drug use review program shall meet the following requirements for covered outpatient drugs and other prescription drugs for which payment may be made under this title:

`(A) PROSPECTIVE DRUG REVIEW- The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to the patient, typically at the point-of-sale or point-of-distribution. Each pharmacist shall use the compendia (referred to in subsection (g)(6)) as the pharmacist's source of standards for such review.

`(B) RETROSPECTIVE DRUG USE REVIEW- The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs.

`(C) EDUCATIONAL PROGRAM- The program shall educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs.

`(f) MISCELLANEOUS-

`(1) EXCLUSION OF CERTAIN DRUG ASSOCIATED WITH EXCLUSIVE PATIENT MONITORING SERVICES- Nothing in this title shall be construed as requiring a State to provide medical assistance for covered outpatient drugs of a manufacturer which requires, as a condition for the purchase of the drugs, that the manufacturer be paid for associated services or tests (such as patient monitoring systems) provided only by the manufacturer or its designee.

`(g) DEFINITIONS- In this section:

`(1) AVERAGE MANUFACTURER PRICE- The term `average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug by retail pharmacies or by wholesalers for drugs distributed to the retail pharmacy class of trade.

`(2) COVERED OUTPATIENT DRUG- Subject to the exceptions in paragraph (3), the term `covered outpatient drug' means--

`(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

`(i) which is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

`(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a `new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under sections 301, 302 (a), or 304(a) of such Act to enforce sections 502(f) or 505(a) of such Act; or

`(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling;

`(B) a biological product which--

`(i) may only be dispensed upon prescription,

`(ii) is licensed under section 351 of the Public Health Service Act, and

`(iii) is produced at an establishment licensed under such section to produce such product; and

`(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

`(3) LIMITING DEFINITION- The term `covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to, and in the same setting as, any of the following (and for which payment is made under this title as part of payment for the following and not as direct reimbursement for the drug):

`(A) Inpatient hospital services.

`(B) Hospice services.

`(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

`(D) Physician office visits.

`(E) Outpatient hospital emergency room visits.

`(F) Outpatient surgical procedures.

`(4) NONPRESCRIPTION DRUGS- If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as `over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug may be regarded as a covered outpatient drug.

`(5) MANUFACTURER- The term `manufacturer' means any entity which is engaged in--

`(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

`(B) in the packaging, repackaging, labeling, relabeling, and distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

`(6) MEDICALLY ACCEPTED INDICATION- The term `medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or which is

accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

`(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG-

`(A) DEFINITIONS-

`(i) MULTIPLE SOURCE DRUG- The term `multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

`(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of `Approved Drug Products with Therapeutic Equivalence Evaluations'),

`(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

`(III) are sold or marketed in the State during the period.

`(ii) INNOVATOR MULTIPLE SOURCE DRUG- The term `innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

`(iii) NONINNOVATOR MULTIPLE SOURCE DRUG- The term `noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

`(iv) SINGLE SOURCE DRUG- The term `single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers operating under the new drug application.

`(B) EXCEPTION- Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent,

they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

`(C) DEFINITIONS- For purposes of this paragraph--

`(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

`(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

`(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

`(8) STATE AGENCY- The term `State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.'.

(c) FUNDING-

(1) DRUG USE REVIEW PROGRAMS- Section 1903(a)(3) of such Act (42 U.S.C. 1936b(a)(3)) is amended--

(A) by striking `plus' at the end of subparagraph (C) and inserting `and', and

(B) by adding at the end the following new subparagraph:

`(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(e); plus'.

(2) TEMPORARY INCREASE IN FEDERAL MATCH FOR ADMINISTRATIVE COSTS- The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (e)) of such Act shall be 75 percent, rather than 50 per centum.

(d) REPORTING OF INFORMATION BY HEALTH MAINTENANCE ORGANIZATIONS- Section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended--

(1) by striking `and' at the end of clause (vii),

(2) by striking the period at the end of clause (viii) and inserting `; and', and

(3) by adding at the end the following new clause:

`(ix) such contract provides for the quarterly reporting to the State and the Secretary (in a manner specified by the State, consistent with any standard reporting format established by the Secretary under section 1927(b)(2)(A)) concerning the identity and dosages of covered outpatient drugs prescribed by the entity under this title.'.

(e) STUDIES-

(1) STUDY OF THERAPEUTIC INTERCHANGABILITY-

(A) The Secretary of Health and Human Services shall undertake a study of therapeutic interchangeability among pharmaceutical products and biologicals.

(B) The study shall include a review of--

(i) the scientific and clinical foundation for the concept of therapeutic interchangeability among drug products;

(ii) the use of therapeutic interchangeability by health care institutions, including Federally funded hospitals and health care programs, in managing drug therapy and containing costs;

(iii) current outpatient prescription drug system which employ therapeutic interchangeability for the purpose of developing a therapeutic formulary and the patient safeguards incorporated into such a system;

(iv) how the concept of therapeutic interchangeability can be used by Federally-funded programs and other third-party insurers for the purpose of managing drug therapy and containing costs; and

(v) mechanisms that might be developed on the national and State level to make determinations of therapeutic interchangeability of drug products.

(C) By not later than June 1, 1992, the Secretary shall submit a report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives concerning the study conducted under this paragraph.

(2) REPORT ON DRUG PRICING- By not later than May 1 of each year, the Comptroller General shall submit to the Secretary of Health and Human Services, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans' Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

*END*

S 3029 IS

101st CONGRESS

2d Session

**S. 3029**

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

**IN THE SENATE OF THE UNITED STATES**

**September 12 (legislative day, SEPTEMBER 10), 1990**

[+] FEEDBACK

Mr. PRYOR introduced the following bill; which was read twice and referred to the Committee on Finance

**A BILL**

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

## SECTION 1. SHORT TITLE.

This Act may be cited as the `Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990'.

## SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS- The Congress finds as follows:

(1) State medicaid programs are under severe and increasing financial pressure as a result of drug price inflation.

(2) States have been forced to respond to this situation with undesirable measures to contain costs, such as excluding categories of drug products from coverage and increasing beneficiary copayments. These actions limit access to needed medications for poor elderly, minority, and other vulnerable low-income populations who rely on the medicaid program.

(3) Drug manufacturers offer, as a matter of business practice, substantial discounts on drug products to many large-volume purchasers.

(4) Medicaid's status as a publicly-funded program for the poor which purchases a large volume of prescription pharmaceuticals entitles it to earn these substantial discounts to the medicaid program.

(5) Drug manufacturers currently discriminate against medicaid recipients by refusing to

offer similar discounts to the medicaid program.

(6) Certain drug manufacturers have proposed their own plans for medicaid drug program cost containment that cannot be counted on to achieve cost savings for medicaid and have the potential to create serious access problems to drugs for medicaid beneficiaries.

(b) PURPOSES- The purposes of this Act are--

(1) to assure that State medicaid drug cost control initiatives are focused on drug manufacturer prices and that medicaid beneficiaries and providers do not absorb the cost of such initiatives;

(2) to obtain the best prices for pharmaceuticals dispensed under medicaid programs;

(3) eliminate drug manufacturer discrimination against low-income groups in the United States by requiring discounts on drug products of a manufacturer as a condition of Federal financial participation under the medicaid program for drug products of the manufacturer;

(4) to provide incentives for drug manufacturers to maintain substantial discounts for medicaid programs; and

(5) to enhance physicians' ability to prescribe and the patients' ability to receive needed medications under the medicaid program.

## SEC. 3. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) IN GENERAL-

(1) DENIAL OF FEDERAL FINANCIAL PARTICIPATION UNLESS REBATE AGREEMENTS AND DRUG USE REVIEW IN EFFECT- Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended--

(A) by striking the period at the end of paragraph (9) and inserting `; or', and

(B) by inserting after paragraph (9) the following new paragraph:

`(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless (A) except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927(a) with respect to the drugs so dispensed in all States, and (B) effective January 1, 1993, the State provides for drug use review in accordance with section 1927(g).'.

(2) PROHIBITING STATE PLAN DRUG ACCESS LIMITATIONS FOR DRUGS COVERED UNDER A REBATE AGREEMENT- Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended--

(A) by striking `and' at the end of paragraph (52),

(B) by striking the period at the end of paragraph (53) and inserting `; and', and

(C) by inserting after paragraph (53) the following new paragraph:

`(54)(A) provide that, in the case of a manufacturer which has entered into and complies with an agreement under section 1927(a), any formulary or similar restriction

(other than a prior authorization program described in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of the manufacturer which are prescribed for a medically accepted indication (as defined in section 1927(l)(6)), and

`(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of subsections (d) through (f) and (g)(4) of section 1927. '.

(3) REBATE AGREEMENTS FOR COVERED OUTPATIENT DRUGS, DRUG USE REVIEW, AND RELATED PROVISIONS- Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section:

## `PAYMENT FOR PRESCRIBED DRUGS

`SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT-

`(1) IN GENERAL- In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of all the States. If a manufacturer has not entered into such an agreement before January 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

`(2) EFFECTIVE DATE- Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

`(3) AUTHORIZING PAYMENT, WITH PRIOR AUTHORIZATION, FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS- Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if the physician has obtained approval of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d).

`(4) EFFECT ON EXISTING AGREEMENTS- In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement may remain in effect, and shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State establishes to the satisfaction of the Secretary that the agreement provides for rebates that are at least as large as the rebates otherwise required under this section.

`(b) TERMS OF REBATE AGREEMENT-

`(1) QUARTERLY REBATES-

`(A) IN GENERAL- A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, for a rebate each calendar quarter in the amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter. Such a rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for that quarter.

`(B) OFFSET AGAINST MEDICAL ASSISTANCE- Amounts received by a State as rebates under this section in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for

purposes of section 1903(a)(1); except that States shall provide, in a manner specified by the Secretary, for payments to the Prescription Drug Policy Review Commission (established under subsection (i)) of such portion of such rebates as may be specified in appropriation Acts.

`(2) STATE PROVISION OF INFORMATION-

`(A) STATE RESPONSIBILITY- Each State agency under this title shall report to each manufacturer, not later than 60 days after the end of each calendar quarter and in a form consistent with any standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter, and shall promptly transmit a copy of such report to the Secretary.

`(B) LIMITATIONS ON AUDIT- A manufacturer has the right to an audit only of the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

`(C) NOTICE TO SECRETARY- Each State agency shall notify the Secretary within 30 days after the date each rebate is received under this section.

`(3) MANUFACTURER PROVISION OF PRICE INFORMATION-

`(A) IN GENERAL- Each manufacturer with an agreement in effect under this section shall report to the Secretary (and make available upon request to each State agency)--

`(i) not later than 30 days after the last day of each quarter (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (l)(1)) and (for single source drugs and innovator multiple source drugs) the manufacturer's best price (as defined in subsection (c)(3)(A)) for covered outpatient drugs for the quarter, and

`(ii) not later than 30 days after the date of entering into an agreement under this section on the best price (as defined in subsection (c)(3)(B)) as of September 1, 1990 for each of the manufacturer's covered outpatient drugs.

`(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE- The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary to verify average manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $10,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(C) PENALTIES-

`(i) FAILURE TO PROVIDE TIMELY INFORMATION- In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the rebate required under the agreement shall be increased by $10,000 for

each day in which such information has not been provided, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

`(ii) FALSE INFORMATION- Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law (including exclusion under section 1128(b)(11)). The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(D) CONFIDENTIALITY OF INFORMATION- Information disclosed by manufacturers or wholesalers under this paragraph is confidential and shall not be disclosed by the Secretary or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

`(4) LENGTH OF AGREEMENT-

`(A) IN GENERAL- A rebate agreement shall be effective for an initial period of 1 year and shall be automatically renewed for an additional 1-year period unless terminated under subparagraph (B).

`(B) TERMINATION-

`(i) BY THE SECRETARY- The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

`(ii) BY A MANUFACTURER- A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until such period (of not more than 1 year) after the date of the notice as the Secretary may provide by regulation.

`(iii) EFFECTIVENESS OF TERMINATION- Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

`(C) DELAY BEFORE REENTRY- In the case of any rebate agreement with a manufacturer under this section which is terminated, a new such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

`(c) AMOUNT OF REBATE-

`(1) IN GENERAL-

`(A) SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- Except as provided in this subsection and subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to single source drugs and innovator multiple source drugs shall be equal to the product of--

`(i) the amount by which (I) the average manufacturer price during the quarter for each dosage form and strength of a covered outpatient drug (after deducting customary prompt payment discounts), exceeds (II) the manufacturer's best price (as defined in paragraph (3)) for such form and strength; and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2)).

`(B) OTHER DRUGS- Except as provided in subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

`(i) 10 percent of the average manufacturer price to wholesalers during the quarter for each dosage form and strength of a covered outpatient drug (after deducting customary prompt payment discounts); and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2).

`(2) MINIMUM AND MAXIMUM REBATE RATES FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- In no case shall the amount of the rebate described in paragraph (1)(A) for a manufacturer for a calendar quarter with respect to single source drugs and innovator multiple source drugs be less than 10 percent, or more than 25 percent of the product of the price described in paragraph (1)(A)(i)(I) and the number of units described in paragraph (1)(A)(ii) for the quarter.

`(3) BEST PRICE DEFINED-

`(A) IN GENERAL- In this subsection, the term `best price' means, for a covered outpatient drug of a manufacturer dispensed in a calendar quarter--

`(i) the lowest price available for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States during the quarter, or

`(ii) the lowest price in effect for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States in effect on September 1, 1990, increased (for calendar quarters beginning on or after January 1, 1991) by the percentage increase in the Consumer Price Index for All Urban Consumers (all items; U.S. city average) from September 1990 to the month before the beginning of the calendar quarter involved,

whichever is lower.

`(B) TREATMENT OF NEW DRUGS- In the case of a covered outpatient drug approved for marketing after September 1, 1990, any reference in subparagraph

(A)(ii) to `September 1, 1990' or `September 1990' shall be a reference to the first day of the first month, and the first month, respectively, during which the drug was marketed and any reference in subsection (b)(3)(A)(ii) to `30 days after the date of entering into an agreement under this section on the best price described in paragraph (3)(B) as of September 1, 1990' shall be a reference to `30 days after the date the drug is first marketed in the United States'.

`(C) COMPUTATION OF LOWEST PRICE- The lowest price described in this paragraph shall be inclusive of cash discounts, free goods, volume discounts, and rebates, shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount.

`(d) LIMITATIONS ON PRIOR AUTHORIZATION PROGRAMS-

`(1) CONDITIONS- A State plan under this title may not require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (l)(6)) unless the system providing for such approval--

`(A) is available to physicians 24 hours a day, 7 days a week, and

`(B) provides an immediate response by telephone or other telecommunication device to an inquiry.

`(2) DELAYED EFFECTIVE DATE- Paragraph (1) shall only apply to prior authorization programs for drugs dispensed on or after April 1, 1991.

`(e) PARTIAL RESTORATION OF PAYMENTS TO PHARMACISTS-

`(1) IN GENERAL- Beginning fiscal year 1991 and ending September 30, 1993, each State plan under this title shall provide, after the end of each fiscal year and in a lump-sum payment, for a payment to pharmacies dispensing covered outpatient drugs under this title during the fiscal year.

`(2) AMOUNT OF PAYMENT- The amount of the payment under this subsection for any fiscal year to a pharmacist shall bear the same ratio to 10 percent of the total amount of rebates received under this section by the State in the fiscal year involved, as the ratio of the number of prescriptions filled by the pharmacy under this title in the fiscal year bears to the total of such number for all pharmacies in the State in the fiscal year, and will be made within 60 days after the end of each fiscal year.

`(f) CHANGES IN REIMBURSEMENT SYSTEM FOR PRESCRIBED DRUGS-

`(1) DISPENSING FEES-

`(A) ANNUAL STUDY- Each State plan shall have conducted, by not later than March 1 of each year (beginning with 1993), a study to determine the cost of dispensing prescriptions for covered outpatient drugs under this title. The study shall include a statistically valid sample of retail pharmacies in the State and shall use a generally accepted method to calculate the cost of dispensing a prescription.

`(B) UPDATING DISPENSING FEES- Beginning on March 1, 1993, and yearly thereafter, each State shall update the payment amounts provided under the State plan for dispensing prescriptions to reflect a reasonable reimbursement fee which is

based on the study of costs of dispensing prescriptions most recently conducted under subparagraph (A).

`(2) NO REDUCTIONS IN REIMBURSEMENT LIMITS- Prior to March 1, 1993, no changes may be made by the Secretary or a State to the formula used to determine the reimbursement limits in effect under this title as of August 1, 1990, which would result in a reduction in the limit relative to either the ingredient cost portion or the dispensing fee portion of the formula, for covered outpatient drugs.

`(3) DENIAL OF FEDERAL FINANCIAL PARTICIPATION IN CERTAIN CASES- The Secretary shall provide that no payment shall be made to a State under section 1903(a) for an innovator multiple-source drug dispensed on or after April 1, 1991, if, under applicable state law, a noninnovator multiple source drug (other than the innovator multiple-source drug) could have been dispensed consistent with such law.

`(g) DRUG USE REVIEW-

`(1) IN GENERAL- In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs and for prescription drugs (other than psychopharmacologic drugs described in section 1919(c)(2)(D)) dispensed to residents of nursing facilities in order to assure that prescriptions (A) are appropriate, (B) are medically necessary, and (C) are not likely to result in adverse medical results.

`(2) DESCRIPTION OF PROGRAM- Each drug use review program shall meet the following requirements for covered outpatient drugs and other prescription drugs:

`(A) PROSPECTIVE DRUG REVIEW- (i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to the patient, typically at the point-of-sale or point of distribution. Each pharmacist shall use the compendia referred to in subsection (l)(6)) as its source of standards for such review.

`(ii) As part of the State's prospective drug use review program under this subparagraph, applicable State law shall establish standards for patient counseling by pharmacists which includes at least the following:

`(I) The pharmacist must offer to discuss with each patient or caregiver (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a new prescription all matters, which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, including at least the following:

`(a) The name and description of the medication.

`(b) The route, dosage, administration, and continuity of drug therapy.

`(c) Special directions for use by the patient as deemed necessary by the pharmacist.

`(d) Common severe adverse effects or interactions that may be encountered, and the action required if they occur.

`(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following patient information:

`(a) Patient name, address, telephone number, date of birth (or age), and gender.

`(b) Patient history where significant, including chronic disease state or states, known allergies and drug reactions, and as current of a comprehensive list of medications and relevant devices as possible.

`(c) Pharmacist comments.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when a patient or caregiver refuses such consultation.

`(B) RETROSPECTIVE DRUG USE REVIEW- The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs.

`(C) APPLICATION OF STANDARDS- The program shall assess data on drug use against explicit predetermined standards and, as necessary, introduce remedial strategies, in order to improve the quality of care, to conserve program funds or personal expenditures, and to control fraud and benefit abuse.

`(D) EDUCATIONAL PROGRAM- The program shall, through its State drug use review board established under paragraph (4), educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs, including such reactions due to--

`(i) interaction of two or more drugs being taken concurrently;

`(ii) concurrent use of two or more drugs from within the same drug use class;

`(iii) excessive or subtherapeutic daily dose;

`(iv) allergies to drugs;

`(v) interaction of prescribed drugs with drugs available without a prescription (commonly referred to as `over-the-counter' drugs);

`(vi) incorrect drug dosage or duration of drug treatment; and

`(vii) interaction between a drug and an existing disease State.

`(3) USE OF INFORMATION BY SECRETARY- At the earliest possible date after the date of the enactment of this section, the Secretary shall use the information on individual prescription claims which is available in the mechanized claims processing and information retrieval system provided for in section 1903(r) in order to perform retrospective drug use reviews described in paragraph (2)(B); except that information which comes to the Secretary's attention through a State's mechanized claims processing and information retrieval system and which suggests a pattern of inappropriate or medically unnecessary prescribing or dispensing of covered outpatient drugs shall be referred to the drug use review board of the concerned State, which shall

use the information as the basis for targeting educational outreach and intervention under paragraph (4). This authority of the State board is not to be construed to limit any existing authority of the Secretary or the State to respond to problems identified in the course of the prospective drug use reviews performed under this subsection.

`(4) STATE DRUG USE REVIEW BOARD-

`(A) ESTABLISHMENT AND MEMBERSHIP- Each State shall provide for the establishment of a drug use review board. The chairman of the board and a majority of the membership shall be practicing physicians. The remaining membership shall include clinical pharmacologists and pharmacists. All members shall have recognized knowledge and expertise in one or more of the following:

`(i) The appropriate prescribing the dispensing of covered outpatient drugs.

`(ii) Drug prescribing and dispensing.

`(iii) Drug use review.

`(iv) Medical quality assurance.

`(B) ANNUAL REPORT- Each State drug use review board shall prepare and submit to the Secretary on an annual basis a report of the activities of the Board to identify the nature and the scope of the retrospective drug use review program, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's retrospective program.

`(C) EDUCATIONAL OUTREACH AND INTERVENTION- Each State drug use review board shall, either directly or through contracts with utilization and quality control peer review organizations, as defined in section 1152, or with State medical societies, conduct ongoing educational outreach and intervention programs for physicians and pharmacists, targeted toward problems or individuals identified in the course of retrospective drug use reviews performed under this subsection, and evaluate the success of the interventions and make modifications as necessary. These educational outreach and intervention programs shall include at least--

`(i) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

`(ii) use of face-to-face interventions by health professionals with prescribers and dispensers, including follow up visits and discussion of optimal prescribing or dispensing practices; and

`(iii) enhanced review or monitoring of prescribers or dispensers exhibiting a pattern of suspected substandard care.

`(h) ELECTRONIC CLAIMS MANAGEMENT-

`(1) IN GENERAL- In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system,

for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

`(2) ENCOURAGEMENT- In order to carry out paragraph (1)--

`(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development and operation of a system described in shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires; through the applicable competitive procurement process in the State, the most efficient and cost-effective telecommunications network and automatic data processing services and equipment; and

`(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

`(i) PRESCRIPTION DRUG POLICY REVIEW COMMISSION-

`(1) IN GENERAL- The Director of the Congressional Office of Technology Assessment (in this subsection referred to as the `Director' and the `Office', respectively) shall provide for the appointment of a Prescription Drug Policy Review Commission (in this subsection referred to as the `Commission'), to be composed of individuals with expertise in the provision and financing of inpatient and outpatient drugs and biologicals. The provisions of title 5, United States Code, governing appointments in the competitive service shall not apply to the appoint of members of the Commission.

`(2) COMPOSITION-

`(A) IN GENERAL- The Commission shall consist of 11 individuals. Members of the Commission shall first be appointed by no later than January 1, 1991, for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

`(B) MEMBERSHIP- The membership of the Commission shall include recognized experts in the fields of health care economics and quality assurance, medicine, pharmacology, pharmacy, and prescription drug reimbursement, as well as at least one individual who is a medicaid recipient.

`(3) ANNUAL REPORTS- The Comission shall submit to the Congress an annual report (by not later than June 1 of each year beginning with 1992) which shall include information and recommendations regarding drug policy issues, such as--

`(A) the scope of coverage and reimbursement for prescribed drugs under this title, including accessibility of drugs to medical assistance recipients;

`(B) the availability and affordability of private insurance for prescription drug costs, the advisability of providing Federal funding to encourage the development of State pharmaceutical assistance plans for the elderly;

`(C) changes in manufacturers' prices for prescribed drugs and pharmacists' charges for covered outpatient drugs; and

`(D) changes in the level and nature of use of covered outpatient drugs by medical assistance recipients, taking into account the impact of such changes on aggregate expenditures under this title.

`(4) SPECIAL REPORT- The Commission shall submit to Congress a report, by not later than December 1, 1993, including information and recommendations concerning--

`(A) methods of payment for drug products, including evaluation of methods of negotiating prices with drug manufacturers, of reimbursing pharmacists for cognitive services and prescription drug products, and other approaches to payment policy;

`(B) methods for assessing the relative therapeutic contribution of new drugs approved for marketing in the United States, including recommendations for expedited coverage under this title for products making a significant contribution to existing drug therapies;

`(C) requirements necessary for efficient program administration, such as uniform drug nomenclature, electronic claims management and payment technologies, and uniform reporting of claims; and

`(D) forms of cost-containment now used by private entities, including an assessment of the documented potential for significant expenditure reductions under this title resulting from price negotiations between manufacturers of drug products which are therapeutic alternates.

`(5) ADMINISTRATIVE PROVISIONS- Section 1845(c)(1) shall apply to the Commission in the same manner as it applies to the Physician Payment Review Commission.

`(6) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this subsection. Rebates provided under agreements under this section shall be available, in the manner specified in subsection (b)(1)(B) to carry out this subsection.

`(j) ANNUAL REPORT AND DATABASE-

`(1) IN GENERAL- Not later than May 1 of each year (beginning with 1992), the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

`(2) DETAILS- Each report shall include information on--

`(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

`(B) the total value of rebates received and number of manufacturers providing such rebates;

`(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

`(D) the effect of inflation on the value of rebates required under this section; and

`(E) trends in prices paid under this title for covered outpatient drugs.

`(3) Medicaid prescription drug data base-

`(A) DEVELOPMENT- Not later than October 1, 1991, the Secretary shall develop and make available for research purposes a medicaid prescription drug data base, which contains information (in a form that protects the confidentiality of information that identifies individual patients or confidential manufacturer information) on each State's program for covered outpatient drugs under this title.

`(B) TRANSMITTAL OF INFORMATION- Each State agency shall transmit to the Secretary such data as may be necessary to carry out this paragraph.

`(C) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this paragraph. Rebates provided under agreements under this section shall be available, in the same manner specified in subsection (b)(1)(B) as such rebates are available to carry out subsection (i), to carry out this subsection.

`(C) EXPENSES- Expenses required to carry out this paragraph in any quarter shall be considered to be amounts expended during such quarter as medical assistance under section 1903(a)(1) and shall be offset against rebates received by States under this section in a manner proportional to the rebates received by each such State.

`(k) MISCELLANEOUS-

`(1) EXCLUSION OF CERTAIN DRUG ASSOCIATED WITH EXCLUSIVE PATIENT MONITORING SERVICES- Nothing in this title shall be construed as requiring a State to provide medical assistance for covered outpatient drugs of a manufacturer which requires, as a condition for the purchase of the drugs, that the manufacturer be paid for associated services or tests (such as patient monitoring systems) provided only by the manfacturer or its designee.

`(2) APPLICATION OF REBATE- If a State elects to provide medical assistance for drugs described in paragraph (1), such drugs shall be subject to the rebate schedule described in subsection (c).

`(l) DEFINITIONS- In this section:

`(1) AVERAGE MANUFACTURER PRICE- The term `average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug by retail pharmacies or by wholesalers for drugs distributed to the retail pharmacy class of trade.

`(2) COVERED OUTPATIENT DRUG- Subject to the exceptions in paragraph (3), the term `covered outpatient drug' means--

`(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

`(i) which is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

`(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical,

similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a `new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of such Act to enforce sections 502(f) or 505(a) of such Act; or

`(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling;

`(B) a biological product which--

`(i) may only be dispensed upon prescription,

`(ii) is licensed under section 351 of the Public Health Service Act, and

`(iii) is produced at an establishment licensed under such section to produce such product; and

`(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

`(3) LIMITING DEFINITION- The term `covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to, and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

`(A) Inpatient hospital services.

`(B) Hospice services.

`(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

`(D) Physician office visits.

`(E) Outpatient hospital emergency room visits.

`(F) Outpatient surgical procedures.

Such term also does not include any such drug or product which is used for a medical indication which is not a medically accepted indication.

`(4) NONPRESCRIPTION DRUGS- If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as `over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug may be regarded as a covered

outpatient drug.

`(5) MANUFACTURER- The term `manufacturer' means any entity which is engaged in--

`(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

`(B) in the packaging, repackaging, labeling, relabeling, and distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

`(6) MEDICALLY ACCEPTED INDICATION- The term `medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

`(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG-

`(A) DEFINITIONS-

`(i) MULTIPLE SOURCE DRUG- The term `multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

`(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of `Approved Drug Products with Therapeutic Equivalence Evaluations'),

`(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

`(III) are sold or marketed in the State during the period.

`(ii) INNOVATOR MULTIPLE SOURCE DRUG- The term `innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

`(iii) NONINNOVATOR MULTIPLE SOURCE DRUG- The term `noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

`(iv) SINGLE SOURCE DRUG- The term `single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers operating under the new drug application.

`(B) EXCEPTION- Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

`(C) DEFINITIONS- For purposes of this paragraph--

`(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendia or other applicable standards of strength, quality, purity, and identity;

`(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

`(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

`(8) STATE AGENCY- The term `State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.'.

(c) FUNDING-

(1) DRUG USE REVIEW PROGRAMS- Section 1903(a)(3) of such Act (42 U.S.C. 1936b(a)(3)) is amended--

(A) by striking `plus' at the end of subparagraph (C) and inserting `and', and

(B) by adding at the end the following new subparagraph:

`(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g); plus'.

(2) TEMPORARY INCREASE IN FEDERAL MATCH FOR ADMINISTRATIVE COSTS- The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (g)) of such Act shall be 75 percent, rather than 50 per centum.

(d) DEMONSTRATION PROJECTS-

(1) PROSPECTIVE DRUG UTILIZATION REVIEW-

(A) The Secretary of Health and Human Services shall provide, through competitive procurement by not later than January 1, 1992, for the establishment of at least 10 statewide demonstration projects to evaluate the efficiency and cost-effectiveness of prospective drug utilization review (as a component of on-line, real-time electronic point-of-sales claims management) in fulfilling patient counseling and in

reducing costs for prescription drugs.

(B) Each of such projects shall establish a central electronic repository for capturing, storing, and updating prospective drug utilization review data and for providing access to such data by participating pharmacists (and other authorized participants).

(C) Under each project, the pharmacist or other authorized participant shall assess the active drug regimens of recipients in terms of duplicate drug therapy, therapeutic overlap, allergy and cross-sensitivity reactions, drug interactions, age precautions, drug regiment compliance, prescribing limits, and other appropriate elements.

(D) Not later than January 1, 1994, the Secretary shall submit to Congress a report on the demonstration projects conducted under this paragraph.

(2) DEMONSTRATION PROJECT ON COST-EFFECTIVENESS OF REIMBURSEMENT FOR PHARMACISTS' COGNITIVE SERVICES-

(A) The Secretary of Health and Human Services shall conduct a demonstration project to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists under title XIX of the Social Security Act, whether or not a drug is dispensed, for drug use review services. For this purpose, the Secretary shall provide for no fewer than 5 demonstration sites and the participation of a significant number of pharmacists.

(B) Not later than January 1, 1995, the Secretary shall submit a report to the Congress on the results of the demonstration project conducted under subparagraph (A).

(e) STUDIES-

(1) STUDY OF THERAPEUTIC INTERCHANGE- ABILITY-

(A) The Secretary of Health and Human Services shall undertake a study of therapeutic interchangeability among pharmaceutical products and biologicals.

(B) The study shall include a review of--

(i) the scientific and clinical foundation for the concept of therapeutic interchangeability among drug products;

(ii) the use of therapeutic interchangeability by health care institutions, including Federally funded hospitals and health care programs, in managing drug therapy and containing costs;

(iii) current outpatient prescription drug systems which employ therapeutic interchangeability for the purpose of developing a therapeutic formulary and the patient safeguards incorporated into such a system;

(iv) how the concept of therapeutic interchangeability can be used by Federally-funded programs and other third-party insurers for the purpose of managing drug therapy and containing costs; and

(v) mechanisms that might be developed on the national and State level to make determinations of therapeutic interchangeability of drug products.

(C) By not later than June 1, 1992, the Secretary shall submit a report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives concerning the study conducted under this paragraph.

(2) STUDY OF DRUG PURCHASING AND BILLING ACTIVITIES OF VARIOUS HEALTH CARE SYSTEMS-

(A) The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the medicaid program. The study shall compare the ingredient costs of drugs for medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies.

(B) By not later than May 1, 1991, the Comptroller General shall report to the Secretary of Health and Human Services, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the study conducted under subparagraph (A).

(3) REPORT ON DRUG PRICING- By not later than May 1 of each year, the Comptroller General shall submit to the Secretary of Health and Human Services, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans' Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

*END*

**THE MEDICAID PRESCRIPTION DRUG FAIR ACCESS AND PRICING ACT OF 1990 -- HON. JIM COOPER (Extension of Remarks - September 13, 1990)**

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**HON. JIM COOPER**

**in the House of Representatives**

*WEDNESDAY, SEPTEMBER 12, 1990*

- Mr. COOPER. Mr. Speaker, sometimes an idea comes along that is so simple, so powerful, and so compelling that people wonder why it hadn't been considered years before. Our colleague in the other body, Senator **Pryor**, has come up with such an idea, and my House colleague **Ron Wyden,** and I, are introducing legislation today in the House to implement that idea.

- The idea is simple. When the U.S. Government is a large purchaser of something, it should be able to negotiate to get either the lowest possible price, or at least as good a price as other bulk purchasers are getting. The U.S. Government should be run more like a business, which almost always bargains to get the best possible deal. The converse of that is the Government should never blindly pay the highest possible prices, thus wasting precious taxpayer dollars, because it is too stupid to get a discount.

- In many cases, the U.S. Government does get reduced rates. When the Federal Government purchases everything from automobiles to fountain pens, even renting hotel rooms, a substantial discount is available from the supplier.

- I think most Americans would be shocked to learn that the U.S. Government, through the Medicaid Program, is the top purchaser of prescription drugs in America and yet rarely gets the discounts that smaller purchasers get. In fact, we taxpayers usually end up paying top dollar. In most cases, Government hasn't even tried to get lower prices. We've let the drug companies tell us how much they would like to be paid, and we have paid them with no questions asked.

- The cost of this extravagance has been largely hidden, but it has been extraordinary. This unlegislated, unrecorded subsidy to the pharmaceutical industry has cost the Nation's Medicaid Program, and thus the Nation's taxpayers and poor, an estimated $2.5 billion over 5 years, according to the Congressional Budget Office and the Office of Management and Budget. Hundreds of million dollars every year have not reached the poor in America because the U.S. Government did not get a better deal from U.S. drug companies.

- This is not to say that the U.S. pharmaceutical industry is all bad. Far from it. It leads the world in innovation and quality. Countless lives have been saved and improved as a result of the industry's research and product development. Being the world leader is not cheap. It takes money and lots of it. But the drug companies have found one way of getting lots of money from the Federal Government without the need for an appropriation or even an

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- explanation. By simply refusing to bargain with the Federal Government, they have created a secret subsidy for themselves that is unfair to the taxpayers and poor of America.

- The U.S. pharmaceutical industry gives discounts to the vast majority of hospitals in America

because they are smart enough to demand them. The industry also gives lower prices to the Veterans' Administration hospitals and to health maintenance organizations. Why not to their biggest customer, the U.S. Government's Medicaid Program?

- Some States have caught on to this game and have begun the bargaining process. But they have often been forced to resort to formularies, restrictive lists of drugs that Medicaid patients may be prescribed, in order to gain a bargaining advantage with the drug companies.

- The Federal Government has the power and the responsibility to make sure that every State, every taxpayer, and every poor person, is protected from wasteful spending in the Medicaid Program. The Pryor bill, which we are introducing today, achieves these savings without harming the legitimate interests of either poor citizens or drug companies. This bill should be distinguished from an earlier bill, S. 2605, which Senator **Pryor** introduced on the same subject but with a significantly different set of solutions.

- This bill we are introducing today assures access to the best prescription drugs on the market for our Nation's poor. No one need fear the creation of a system of second-class drugs for our Nation's poor. In fact, the estimated budget savings of $1.6 billion over 5 years that this bill will produce should allow the Medicaid Program to reach out to many more people in order to serve them better.

- Major companies in the U.S. pharmaceutical industry itself have shown that they can live quite well when they give discounts to their largest customer. Several leading drug manufacturers have offered voluntarily to treat the U.S. Government as they do their other large customers, instead of discriminating against it. Unfortunately, these voluntary industry initiatives, while commendable, do not go far enough and lack adequate safeguards. To be sure, the Pharmaceutical Manufacturers Association is still against the legislation, as you would expect a trade association to be. But I feel that it is losing more and more of its members on the issue. These companies expect discounts from their suppliers; the Federal Government expects discounts from its suppliers.

- The leadership of the pharmaceutical industry will be tested by the manner in which it wages this fight. Will it sink to the lowest common denominator and fight to the last breath of the last company that wants to preserve this hidden and unfair subsidy? Or will it be thankful for the many years the U.S. Government has paid it top dollar, and argue for open, efficient subsidies that it is prepared to defend in public and on the merits?

- To be honest with you, the first skirmishes have not been encouraging.

- A very common tactic has been used: Discredit the first Pryor bill in the hopes that all subsequent legislation, such as the bill we are introducing today, will either not be noticed or discredited.

- Another tactic: Don't work with the Congress to improve the legislation and discourage those companies who are willing to; make Congress figure out everything on its own.

- Efforts have even been made by the pharmaceutical industry to convince our Nation's poor that they are better served with the current system, in which our Nation's Medicaid Program is hundreds of millions smaller than it could be if we did not secretly funnel that money to the pharmaceutical industry.

- Efforts have also been made to hide the fact that so many of the new and expensive drugs being introduced today are so similar to existing drugs that they are little more than an excuse for a price increase. So much of our technological talent is being wasted on `me-too' drugs that cost a lot more but don't cure a lot more.

- I would hope that this is an issue that businessmen in the pharmaceutical industry would treat as businessmen. Don't discriminate against your biggest customer, even if it is the Federal Government. Don't treat Uncle Sam like Uncle Sucker. Why? Because we all lose as taxpayers and as a nation when we exploit our own Government.

- I am not an enemy of the pharmaceutical industry. In fact, I have generally supported their initiatives. I am open to any argument they want to make for open, targeted subsidies to help it bring needed drugs to market. I am an enemy of waste, and of secret subsidies at the taxpayers' expense. The pharmaceutical industry of America needs to treat our taxpayers with more respect and offer them, and the poor of America, at least the discounts that they offer to other groups.

- I thank again my colleague, **Ron Wyden**, of Oregon, for joining me in this importan[+] FEEDBACK legislation.

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*END*