UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,
and THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

AFFIDAVIT OF BRADLEY S. FOLEY IN SUPPORT OF DEFENDANT JENNIFER KING VASSEL'S MOTION IN LIMINE THAT THE PRESCRIPTION OF OFF-LABEL USE OF FDA APPROVED PRESCRIPTION MEDICATION WAS MEDICAID FRAUD

STATE OF WISCONSIN)
) ss.
COUNTY OF MILWAUKEE)

BRADLEY S. FOLEY, being duly sworn under oath, deposes and states as follows:

1. I am one of the attorneys representing defendant Jennifer King Vassel in the above-referenced action and am authorized to make this affidavit on her behalf.

2. Attached as Exhibit A is a true and accurate copy of H. Rep. No. 881, 101st Congress, 2d Session at 98, reprinted in U.S. Congress and Administrative News, p. 2110.

3. Attached as Exhibit B is a true and accurate copy of the United States Pharmacopeia-Drug Information 2005, "Description and Limitations of Information Included," located on page two.

4. Attached as Exhibit C is a true and accurate copy of a November 8, 2013 emails between an assistant United States Attorney and the plaintiff's attorney.

5. Attached as Exhibit D is a true and accurate copy of United States Pharmacopeia-

Drug Information 1997, Volume II, Advice for the Patient, Notice Section.

6. Attached as Exhibit E is a true and accurate copy of the Drugdex Warranty and Disclaimer.

s/Bradley S. Foley
Bradley S. Foley

Subscribed and sworn to before me
this 25th day of November, 2013.

s/Carrie Wentland
Notary Public, State of Wisconsin
My Commission expires: 1/19/14

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.

HOUSE REPORT NO. 101-881

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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 810, 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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Additional Views.

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. 810, 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.

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 I—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

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 payor 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 [4]	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 [4]	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 (offsetting 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, $37.50; 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-

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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.

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Volume I

Drug Information for the Health Care Professional

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USP DI

25TH EDITION

Preface

The *USP DI*, originally developed by the United States Pharmacopeia (USP), was created in response to unmet information needs of both professionals and patients in terms of the safe and effective use of medication once it was prescribed. The first edition was published in 1980. From one book in 1980, it grew to two volumes in 1983, and three volumes in 1989. On September 17, 1998, the USP Board of Trustees entered into agreements with Thomson MICROMEDEX for the sale of the *USP DI* Volume I and Volume II databases and licensing of the *USP DI* trademarks. At that time, USP continued to have editorial involvement in the creation of content for Volume I and Volume II.

In May of 2004, Thomson MICROMEDEX and USP modified their relationship. As a result of this modification, USP no longer has editorial review responsibilities with regard to Volume I and Volume II content. Thomson MICROMEDEX now entirely creates and maintains the drug monographs contained in the Volumes.

USP DI is, and always will be, a work in progress. The information is under constant revision. This twenty-fifth edition incorporates the experiences and comments provided by previous editions. New drug monographs and information have been added, and the existing text has been reviewed for changes and revised accordingly.

Development of the 2005 *USP DI*

The USP DI is a comprehensive collection of clinically relevant, established information about each drug. However, it is far more than that. It is also a premier source for off-label use information. The information included represents generally accepted facts about each medication as well as information that represents the clinical judgments of professionals based on the best available evidence placed in the context of medical practice concerns.

For further information about *USP DI* or to comment on how information published in this volume might better meet your information needs, please contact:

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6200 S. Syracuse Way
Suite 300
Greenwood Village, CO 80111-4740
Telephone: (303) 486-6400
Telefax: (303) 486-6464
http://www.micromedex.com/support/request

Organization of *USP DI*

USP DI comprises three distinct volumes. The first volume, *Drug Information for the Health Care Professional,* includes the drug information monographs arranged in alphabetical order. The Volume I general index includes established names, cross-references by brand names (both U.S. and Canadian), and older nonproprietary names. In addition, an indications index, off-label use indices and appendices presenting categories of use and other useful information are included. The second volume, *Advice for the Patient®,* includes the lay language versions of the patient consultation guidelines found in Volume I. These lay language versions are intended to be used at the discretion of the health care provider as an aid to patient consultation if written information would be of benefit or if it is requested by the prescriber. Brand and generic names are cross-referenced in the index of *Advice for the Patient.* The third volume, *Approved Drug Products and Legal Requirements* is owned and published by USP and Thomson MICROMEDEX is a distributor of that volume. It reproduces information from the Food and Drug Administration on therapeutic equivalence and other requirements relating to drug product selection. The third volume includes USP and NF legal requirements for labeling, storage, packaging, and quality for drugs. It also contains those portions of the Federal Controlled Substances Act Regulations, the Poison Prevention Packaging Act and Regulations, and the FD&C Act provisions relating to drugs for human use, and the Current Good Manufacturing Practice Regulations that are most relevant to the physician, pharmacist, nurse, and other health care professionals. However, the reader should review all applicable laws and regulations in the decision-making process.

The individual Volume I monograph covers the basic information that is applicable to that substance when used for a specific area of effect (e.g., Systemic). Information that is unique to a specific dosage form of the base substance is then included under that specific dosage form heading. To illustrate this approach, assume that DRUG X is used for its systemic effects and its topical effects. Also assume that the drug is available in the following dosage forms: cream, injection, ointment, syrup, and tablet. The *USP DI* Volume I monographs for DRUG X would be organized as follows:

DRUG X (Systemic)
[General information applicable to Drug X's systemic use.]
- Drug X Syrup
- Drug X Tablets
- Drug X Injection
- [Specific information applicable to each of the systemic dosage forms.]

DRUG X (Topical)
[General information applicable to Drug X's topical use.]
- Drug X Cream
- Drug X Ointment
- [Specific information applicable to each of the topical dosage forms.]

Examples of other major headings based on specific area of effect are Dental, Inhalation-Local, Intracavernosal, Mucosal-Local, Nasal-Local, Ophthalmic, Oral-Local, Otic, Parenteral-Local, Rectal-Local, Transdermal-Systemic, or Vaginal use.

Whenever feasible, monographs are grouped under family headings. This permits a sizable saving of space and also allows the practitioner to readily identify differences among agents of the same family. Significant differences are addressed in charts and in Summary of Differences sections.

The following headings and subheadings are employed, where appropriate, in organizing the information for each Volume I monograph:

Category
Indications
- General considerations
- Accepted
- Acceptance not established
- Unaccepted

Pharmacology/Pharmacokinetics
- Physicochemical characteristics
  - Source
  - Molecular weight
  - pKa
  - Solubility
  - Partition coefficient
  - Other characteristics
- Mechanism of action/Effect
- Other actions/effects
- Absorption
- Distribution
- Protein binding
- Biotransformation
- Half-life

Onset of action
Time to peak concentration
Peak serum concentration
Time to peak effect
Duration of action
Elimination
In dialysis

Precautions to Consider
Cross-sensitivity and/or related problems
Carcinogenicity
Tumorigenicity
Mutagenicity
Pregnancy/Reproduction
Fertility
Pregnancy
Labor
Delivery
Postpartum
Breast-feeding
Pediatrics
Adolescents
Geriatrics
Pharmacogenetics
Dental
Surgical
Critical/Emergency care
Drug interactions and/or related problems
Laboratory value alterations
With diagnostic test results
With physiology/laboratory test values
Medical considerations/Contraindications
Patient monitoring

Side/Adverse Effects
Those indicating need for medical attention
Those indicating need for medical attention only if they continue or are bothersome
Those not indicating need for medical attention
Those indicating need for medical attention if they occur after medication is discontinued

Overdose
Clinical effects of overdose
Treatment of overdose

Patient Consultation
Before using this medication
Proper use of this medication
Precautions while using this medication
Side/adverse effects

General Dosing Information
Diet/Nutrition
Bioequivalence information
Safety considerations for handling this medication
For treatment of adverse effects

Dosage forms (each separate)
Usual adult dose
Usual adult prescribing limits
Usual pediatric dose
Usual pediatric prescribing limits
Usual geriatric dose
Strengths usually available
Packaging and storage
Preparation of dosage form
Stability
Incompatibilities
Auxiliary labeling
Caution
Additional information

Selected Bibliography

Description and Limitations of Information Included

USP DI contains selected information and takes into account practice concerns. It is meant to aid the health care professional and the patient in minimizing the risks and enhancing the benefits of the drugs used. Collectively, the *USP DI* is valuable when assessing quality of care. Ultimately, the information required is defined by the practice standards of medicine, pharmacy, nursing, dentistry, and the other health professions as well as by the information needs of the patient.

USP DI is not intended to be "full disclosure" information.

Readers are advised that the information in *USP DI* may contain statements that differ from those in the "full disclosure" information labeling approved or required by the United States or Canadian governments. Readers should also remember that FDA-approved full disclosure information can differ from brand to brand of the same generic drug product. It should not be inferred that the inclusion of information that is not in the approved labeling has been sought or agreed to by the manufacturer.

Selected brand names are included in the monographs as well as in the indexes of both Volumes I and II, for ease of reference purposes only. The inclusion of a brand name is not intended as an endorsement of a particular product. The omission of a particular brand name does not indicate that the agent was judged to be inferior or inadequate. The inclusion of various brands in Volumes I and II bears no relationship to, and is not intended to affect, any applicable brand interchange requirements.

The Veterans Administration medication classification codes (primary and secondary assignments) are included at the beginning of each monograph. See the VA Medication Classification System appendix in *USP DI* Volume I for a detailed description as well as a complete listing of primary and secondary classifications.

Where appropriate, controlled substance classifications are included at the beginning of the monograph. United States schedules include:

Schedule I–No legal medical use is recognized by the U.S. Controlled Substances Act. Use of Schedule I substances for research purposes is permitted with proper registration. Schedule I substances are not included in *USP DI*.
Examples: Heroin, LSD, peyote.

Schedule II–The most stringent classification for drugs recognized by the U.S. Controlled Substances Act as having a legitimate medical use; these drugs are characterized by a very high abuse potential and/or potential for severe physical and psychic dependency. Distribution and inventory are highly controlled; prescriptions are non-refillable. Emergency telephone orders for limited quantities of these drugs are authorized but the prescriber must provide a written, signed prescription order to the pharmacy within 72 hours.
Examples: Amphetamines, anabolic steroids, meperidine, morphine, short-acting barbiturates.

Schedule III–Includes drugs having significant abuse potential, but to a lesser degree than Schedule II substances. Prescriptions can be refilled up to five times within six months after the date of issue if authorized by the prescriber. Telephone orders are permitted.
Examples: Certain barbiturates not included in Schedule II, opiates in combination with other substances such as acetaminophen or aspirin.

Schedule IV–Includes drugs having a low abuse potential. Prescriptions can be refilled up to five times within six months after the date of issue if authorized by the prescriber. Telephone orders are permitted.
Examples: Benzodiazepines, certain long-acting barbiturates, chloral hydrate, pentazocine, propoxyphene.

Schedule V– Includes products having the lowest abuse potential of the controlled substances. No limitations on refills other than those

Brad Foley

From: Ward, Stacy G. (USAWIE) <Stacy.G.Ward@usdoj.gov>
Sent: Friday, November 08, 2013 3:51 PM
To: Jim Gottstein
Cc: Brad Foley; Mark Larson; 'Thomas L. Storm'; tobywatson@gmail.com; 'Rebecca Gietman'; Rebecca Gietman; Thomas L. Storm
Subject: RE: DrugPoints -- Not

Jim: It's not that CMS doesn't have an official position. I am not authorized to speak for CMS and my contacts that I referenced in my original email were not at CMS.

Stacy

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Friday, November 08, 2013 3:48 PM
To: Ward, Stacy G. (USAWIE)
Cc: 'Brad Foley'; 'Mark Larson'; 'Thomas L. Storm'; tobywatson@gmail.com; 'Rebecca Gietman'; jim.gottstein@psychrights.org; Rebecca Gietman; Thomas L. Storm
Subject: RE: DrugPoints -- Not

Thanks Stacy,

I didn't intend to misstate what you said, when I wrote "it does not appear . . ." I don't think I did, but apologize to the extent I did. It is curious that the Centers for Medicare and Medicaid Services doesn't just know the answer. Or have an official position. In any event, at this point, I think we just have to go with the American Hospital Formulary Service and DRUGDEX as the only applicable compendia.

Thank you for your assistance.

Jim

From: Ward, Stacy G. (USAWIE) [mailto:Stacy.G.Ward@usdoj.gov]
Sent: Friday, November 08, 2013 11:18 AM
To: Jim Gottstein
Cc: Brad Foley; Mark Larson; Thomas L. Storm; tobywatson@gmail.com; Rebecca Gietman
Subject: RE: DrugPoints -- Not

Jim: as we discussed, I have checked with a couple of sources and neither of them had heard of DrugPoints being the successor to the U.S. Pharmacopeia. This is not the official position of the Centers for Medicare and Medicaid Services, nor the United States' government. I was simply trying to obtain information to get you off in the right direction.

Stacy Gerber Ward
Assistant United States Attorney
E.D. Wisconsin

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Friday, November 08, 2013 1:59 PM
To: Ward, Stacy G. (USAWIE)
Cc: jim.gottstein@psychrights.org; Brad Foley; Mark Larson; Thomas L. Storm; tobywatson@gmail.com; Rebecca

Gietman
Subject: DrugPoints -- Not

Hi Stacy,

Thanks for following up on my question and advising me that it does not appear DrugPoints or any other publication is the successor to United States Pharmacopeia–Drug Information, leaving just the American Hospital Formulary Service Drug Information, and DRUGDEX as the compendia incorporated by reference into 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i). *See*, *U.S. v. King-Vassel,* 728 F.3d 707, 716 (2013)

James B. (Jim) Gottstein, Esq.
President/CEO

Psych Rights
LAW PROJECT FOR PSYCHIATRIC RIGHTS

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http://psychrights.org/

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging and electroshock. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

VOLUME II

Advice for the Patient®

Drug Information in Lay Language

USP DI®

1997

17TH EDITION

By authority of the United States Pharmacopeial Convention, Inc.

Notice:
The information about the drugs contained herein is general in nature and is intended to be used in consultation with your health care providers. It is not intended to replace specific instructions or directions or warnings given to you by your physician or other prescriber or accompanying a particular product. The information is selective and it is not claimed that it includes all known precautions, contraindications, effects, or interactions possibly related to the use of a drug. The information may differ from that contained in the product labeling which is required by law. The information is not sufficient to make an evaluation as to the risks and benefits of taking a particular drug in a particular case and is not medical advice for individual problems and should not alone be relied upon for these purposes. Since the inclusion or exclusion of particular information about a drug is judgmental in nature and since opinion as to drug usage may differ, you may wish to consult additional sources. Should you desire additional information or if you have any questions as to how this information may relate to you in particular, ask your doctor, nurse, pharmacist, or other health care provider.

Since new drugs are constantly being marketed and since previously unreported side effects, newly recognized precautions, or other new information for any given drug may come to light at any time, continuously updated drug information sources should be consulted as necessary. USP updates this main volume of *Advice for the Patient* with the monthly *USP DI Update*, a publication presenting selected new and revised information.

There are many brands of drugs on the market. The listing of selected brand names is intended only for ease of reference. The inclusion of a brand name does not mean the USPC has any particular knowledge that the brand listed has properties different from other brands of the same drug, nor should it be interpreted as an endorsement by the USPC. Similarly, the fact that a brand name has not been included does not indicate that that particular brand has been judged to be unsatisfactory or unacceptable.

If any of the information in this book causes you special concern, do not decide against taking any medicine prescribed for you without first checking with your doctor.

About USP

The information in this volume is prepared by the United States Pharmacopeia (USP), the organization that sets the official standards of strength, quality, purity, packaging, and labeling for medical products used in the United States.

The United States Pharmacopeia is an independent, not-for-profit corporation composed of delegates from the accredited colleges of medicine and pharmacy in the U.S.; state medical and pharmaceutical associations; many national associations concerned with medicines, such as the American Medical Association, the American Nurses Association, the American Dental Association, the National Association of Retail Druggists, and the American Pharmaceutical Association; and various departments of the federal government, including the Food and Drug Administration. Other members represent the public. USP was established 177 years ago, and is the only national body that represents the professions of both pharmacy and medicine.

The first convention came into being on January 1, 1820, and within the year published the first national drug formulary of the United States. The *U.S. Pharmacopeia* of 1820 contained 217 drug names, divided into two groups according to the level of general acceptance and usage.

When Congress passed the first major drug safety law in 1906, the standards recognized by that statute were those set forth in the *United States Pharmacopeia* and in the *National Formulary*. Today, the *USP* and *NF* continue to be the official U.S. compendia for standards for drugs and for the inactive ingredients in drug dosage forms. The *United States Pharmacopeia* is the world's oldest regularly revised national pharmacopeia and is generally accepted as being the most influential.

The work of the USP is carried out by the Committee of Revision. This committee of experts is elected by the members and currently consists of 138 outstanding physicians, pharmacists, dentists, nurses, chemists, microbiologists, and other individuals particularly qualified to judge the merits of drugs and the standards and information that should apply to them. Committee members serve without pay and are assisted by numerous advisory panels, other outside reviewers, and USP staff.

About *USP DI*

Advice for the Patient is Volume II of *USP DI*. Volume I contains drug use information in technical language for the physician, dentist, pharmacist, nurse, or other health care provider, and Volume II is its lay language counterpart for use by consumers. Volume III provides information on approved drug products and legal requirements. The monthly *USP DI Update* keeps all volumes up to date with selected new drug entries and related information. Together, the volumes form the foundation of a coordinated approach to drug-use education. Many health care providers, institutions, and associations in the United States and Canada provide individual drug leaflets based on *Advice for the Patient*. Spanish translations for many medicines are also available.

USP DI was first published in 1980. It is continuously reviewed and revised and is intended for use by prescribers, dispensers, and consumers of medications. The information is developed by the consensus of the USP Committee of Revision and its Advisory Panels and anyone, including users of medicines, may contribute through review and comment on drafts of the monographs when they are published for comment in *USP DI Review*, a part of the monthly *USP DI Update*.

For further information about *USP DI* or to comment on how the information published in this volume might better meet your information needs, please contact: USP Division of Information Development, 12601 Twinbrook Parkway, Rockville, Maryland 20852, (301) 816-8351.

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