



**Healthcare Reform  
Reference Guide  
2010**

**Summary of H.R. 3590 as Amended by H.R. 4872**



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# H.R. 3590 as Amended by H.R. 4872

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## MEDICARE (H.R. 3590, Sec. 3101-3602)

### 2010

- Provide a **\$250 rebate** to Medicare beneficiaries who reach the **Part D coverage gap in 2010** and gradually eliminate the Medicare Part D coverage gap by 2020.
- **Expand Medicare** to individuals exposed to environmental health hazards.

### 2011

- Manufacturers to provide a **50% discount** on brand-name prescriptions filled in the Medicare Part D coverage gap.
  - Begin phasing-in federal subsidies for generic prescriptions filled in the Medicare Part D coverage gap
- Provide a **10% Medicare bonus** payment to primary care **physicians** and to general **surgeons** practicing in health professional shortage areas.

### 2013

- Begin phasing-in **federal subsidies for brand-name prescriptions** filled in the Medicare Part D coverage gap (to 25% in 2020, in addition to the 50% manufacturer brand-name discount).
- **Pilot program** is established, evaluates paying a bundled payment for acute, inpatient hospital services, physician services, outpatient hospital services, and post acute care services.

### 2014

- **Reduce** Medicare DSH payments by **75%**
  - Increase payments over time based upon the % of uninsured population and the amount of uncompensated care provided.

## MEDICAID (H.R. 3590, Sec. 2501)

### 2010

- **Increase** the **Medicaid drug rebate %** for brand name drugs to **23.1%**
  - **Exception:** rebates for clotting factors and drugs approved exclusively for pediatric use increases to 17.1%.
- **Increase** the **Medicaid rebate** for non-innovator, multiple source drugs to **13% of AMP**
  - Extend drug rebate to Medicaid managed care plans

### 2011

- Prohibit federal payments to states for Medicaid services related to health care acquired conditions.
- State balancing incentive program

## 2013

- **Increase Medicaid payments** for primary care services provided by primary care doctors for 2013 and 2014 with **100%** federal funding.

## 2014

- **Expand Medicaid** to all individuals under age 65 with incomes up to 133% FPL based on modified adjusted gross income.
- **Reduce** states' Medicaid DSH allotments

### **Medicaid Unit Rebate Amount Line Extension - (H.R. 4872, Sec. 1206)**

The House-passed reconciliation bill requires a potential substitute Medicaid rebate calculation for "line extensions" of oral solid dosage forms of innovator products. For these products, the Medicaid rebate will be the greater of:

- (a) the usual calculation or
- (b) AMP times the highest additional rebate for any strength of the original expressed as percentage of AMP.

### **Physician Ownership/Reporting/and Other Transparency - (H.R. 3590, Sec. 6002) better known as the Physician Sunshine Payment Act**

If providing a payment or other transfer of value to a covered entity, a Manufacturer must submit:

- The name of the covered recipient.
- The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
- The amount of the payment or other transfer of value.
- The dates on which the payment or other transfer of value was provided to the covered recipient.
- A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
  - cash or a cash equivalent
- In-kind items or services
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
  - Any other form of payment or other transfer of value (as defined by the Secretary).
- A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
  - Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel (including the specified destinations)

- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grant; or
  - Any other nature of the payment or other transfer of value (as defined by the Secretary).
- If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.
- Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

Monetary **penalties** for non-compliance can range from \$10,000 – \$1,000,000. See section 1128G if you have specific questions regarding penalties.

**More Information:**

- Physician ownership-referral (H.R. 4872, Sec. 1106)
  - Changes to December 31, 2010 the date after which physician ownership of hospitals to which they self refer is prohibited and provides a limited exception to the growth restrictions for grandfathered physician owned hospitals that treat the highest percentage of Medicaid patients in their county (and are not the sole hospital in a county).
- Drug, device, biological and medical supply manufacturers must report gifts and other transfers of value made to a physician, physician medical practice, a physician group practice, and/or a teaching hospital.
- Referring physicians for imaging services must inform patients in writing that the individual may obtain such service from a person other than the referring physician, a physician who is a member of the same group practice, or an individual who is supervised by the physician or by another physician in the group
- Prescription drug makers and distributors must report to the HHS Secretary information pertaining to drug samples currently being collected internally.
- Pharmacy benefit managers (PBM) or health benefits plans that provide pharmacy benefit management services that contract with healthy plans under Medicare or the Exchange must report information regarding the generic dispensing rate; rebates, discounts, or price concessions negotiated by the PBM.

**Drug Sampling; Reporting – (H.R. 3590, Sec. 6004)**

Beginning in 2012, no later than April 1<sup>st</sup> of each year each manufacturer and authorized distributor of an applicable drug shall submit to the secretary the following information from the preceding year:

- In the case of a manufacturer or authorized distributor which makes distributions by mail or common carrier reports:
  - Identity and quantity of drug samples requested and the identity and quantity of drug samples distributed, aggregated by:
    - The name, address, professional designation, and signature of practitioner making the request
- In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier reports:
  - The identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by:
    - The name, address, professional designation, and signature of the practitioner making the request

### **Pharmacy benefit managers transparency requirements – (H.R. 3590, Sec. 6005)**

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq) is amended by inserting after section 1150 the following new section:

The Act requires that pharmacy benefit managers (“PBM”) provide the Department of Health and Human Services with information including the percentage of all prescriptions that were provided through mail order pharmacies versus retail pharmacies and the percentage of prescriptions where there is a generic drug available and dispensed. This will create transparency into the discounts achieved by PBM which serves as the middleman between the pharmaceutical manufacturers, health insurance plans and the pharmacies.

The reporting requirement applies to health benefits plan that manages prescription drug coverage under contract with (1) a prescription drug plan sponsor of a prescription drug plan or a Medicare Advantage prescription drug plan under Medicare Part D, (2) a qualified health benefits plan offered through a health insurance exchange established under the Act. In addition to mail order and generic information, PBM’s are required to disclose the aggregate amount and types of rebates, discounts or price concessions that are attributable to patient utilization under the plan. PBM’s will also be required to disclose the aggregate amount of rebates, discounts or price concessions that are passed through to the plan sponsor and the total number of prescription that were dispensed. Excluded from this reporting requirement would be: bona fide services fees such as distribution service fees, inventory management fees and fees associated with administrative service agreements and patient care programs.

### **Expanded Participation in the 340B Program – (H.R. 3590, Sec. 7101)**

- **Expansion of Covered Entities** Receiving Discounted Prices – Section 340B of PHS is amended by adding:

- A **children's hospital** excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act
- free-standing **cancer hospital** excluded from the Medicare prospective payment system
- **Critical Access Hospitals**
- **Rural referral centers** (must have disproportionate share adjustment % equal or greater than 8%)
- Prohibition on Group Purchasing Arrangements
- Medicaid Credits on Inpatient Drugs
  - Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients

### **340B Integrity Provisions: (H.R. 3590, Sec. 7102)**

- Quarterly Manufacturer Reporting
  - The reform bill requires the development of a system that will permit the Secretary (presumably the Health Resources and Services Administration, "HRSA") to verify the accuracy of ceiling prices. To this end, the HRSA must publish "precisely defined" standards for the calculation of ceiling prices; regularly compare HHS-calculated ceiling prices with those reported quarterly by manufacturers; perform "spot checks" of sales to Covered Entities; and investigate and resolve pricing discrepancies.
- Refunding Overpayments
  - The new law also includes integrity provisions to require manufacturers to issue refunds to Covered Entities that are overcharged by the manufacturers and to explain why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued. HRSA must then ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and in exceptional circumstances such as erroneous or intentional overcharges for covered drugs.
- Audit Rights and Penalties
  - The new law permits HRSA to selectively audit manufacturers' and wholesalers' compliance with the requirements of the 340B program. It also grants HRSA the authority to impose civil monetary penalties (not to exceed \$5,000 for each instance of overcharging a Covered Entity) in the event of knowing and intentional overcharges.

### **Payments Excluded from AMP – (H.R. 4872, Sec. 1101 & H.R. 3590, Sec. 2503)**

- The new law expands the list of statutory exclusions from AMP. It continues to exclude customary prompt pay discounts paid to wholesalers.

- The reform law excludes *bona fide* service fees paid to wholesalers and RCPs, and gives examples of services that are potentially *bona fide*:
  - Distribution services,
  - Inventory management agreement services,
  - Stocking allowances and administrative services.
- Reimbursement for recalled, expired, damaged, and returned goods is excluded from AMP, as are the associated costs. PBM, MCO, HMO, insurer, hospital, clinic, mail order, LTC and manufacturer price concessions (and where appropriate payments) are all excluded from AMP.
- Finally, discounts under § 1860D-14A (*i.e.*, the Medicare coverage gap discount program) are now officially out of AMP and Best Price.
- All other discounts to wholesalers and retail community pharmacies will be included in AMP.

## Quick Facts/ At a Glance

### **Dual Eligible Coverage and Payment Coordination – (H.R. 3590, Sec. 2602)**

HHS will establish a Federal Coordinated Health Care office.

- Improve coordination among the federal and state governments for individuals enrolled in both programs.

### **Medicare Advantage Part C – (H.R. 3590, Sec. 3311)**

'MA' payments will be based on the average number of bids submitted by insurance plans in each market.

- MA plans will be prohibited from charging beneficiaries cost sharing for covered services greater than what is charged under fee-for-service

### **Medicare Prescription Drug Plan Improvements Part D – (H.R. 3590, Sec. 3315)**

In order to have their drugs covered under the Medicare Part D program, drug manufacturers will provide a **50% discount** to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap beginning July 1, 2010.

- Initial coverage limit in the standard Part D benefit will be expanded by **\$500** for 2010.

### **Pharmacy Reimbursement – (Section 2503)**

Use of **AMP** in Upper Limits – Secretary shall calculate the Federal upper reimbursement limit as no less than 175% of the weighted average of the most recently reported Monthly AMP for pharmaceutically and therapeutically equivalent multiple source drug products.

- **Smoothing process** will be implemented for AMP
  - Similar to ASP smoothing
- Definition of AMP
  - Wholesalers for drugs distributed to retail community pharmacies
  - Retail community pharmacies that purchase drugs direct from the manufacturer

### **Medicare, Medicaid, and CHIP Program Integrity Provisions (H.R. 3590, Sec. 6401-6508)**

The secretary will establish procedures to screen providers and suppliers participating in Medicare, Medicaid, and CHIP

- Providers and suppliers enrolling or re-enrolling will be subject to new requirements including a fee, disclosure of current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a Federal health care program, or has had their billing privileges revoked.
- Secretary of HHS is authorized to deny enrollment in these programs

**Exclusion of Orphan Drugs for Certain Covered Entities (H.R. 4872, Sec. 2302)**

- For the new Covered Entities, the term “covered outpatient drug” would not include a drug designated for rare conditions by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act under the House-passed reconciliation bill.

**Enhanced Medicare and Medicaid Program Integrity Provisions – (H.R. 3590, Section 1128j)**

CMS will include in the integrated data repository (IDR) claims and payment data from Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs (VA) and Defense (DOD), the Social Security Administration, and the Indian Health Service (IHS).

- New penalties will exclude individuals who order or prescribe an item or service, make false statements on applications or contracts to participate in a Federal health care program, or who know of an overpayment and do not return the overpayment.
- Each violation would be subject to a fine of up to \$50,000.
- The Secretary will take into account the volume of billing for a DME supplier or home health agency when determining the size of a surety bond.
- The Secretary may suspend payments to a provider or supplier pending a fraud investigation.
- Health Care Fraud and Abuse Control (HCFAC) funding will be increased by \$10 million each year for fiscal years 2011 through 2020.
- The Secretary will establish a national health care fraud and abuse data collection program for reporting adverse actions taken against health care providers, suppliers, and practitioners, and submit information on the actions to the National Practitioner Data Bank (NPDB).
- The Secretary will have the authority to dis-enroll a Medicare enrolled physician or supplier who fails to maintain and provide access to written orders or requests for payment for durable medical equipment (DME), certification for home health services, or referrals for other items and services.
- The HHS Secretary will expand the number of areas to be included in round two of the DME competitive bidding program from 79 of the largest metropolitan statistical areas (MSAs) to 100 of the largest MSAs, and to use competitively bid prices in all areas by 2016.

**Additional Medicaid Program Integrity Provisions - (H.R. 3590, Sec. 3101-3602)**

States must terminate individuals or entities from their Medicaid programs if the individuals or entities were terminated from Medicare or another state’s Medicaid program.

- Medicaid agencies must exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that:
  - (1) Has failed to repay overpayments

- (2) Is suspended, excluded, or terminated from participation in any Medicaid program
  - (3) Is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.
- Agents, clearinghouses, or other payees that submit claims on behalf of health care providers must register with the state and the Secretary.
- States and Medicaid managed care entities must submit data elements for program integrity, oversight, and administration.
- States must not make any payments for items or services to any financial institution or entity located outside of the United States.

#### **Pharmaceutical Manufacturers Fee**

- The fee applies only to companies with sales of branded prescription drugs in excess of \$5 million per calendar year.
- Brand name pharmaceuticals (H.R. 4872, Sec. 1404)
  - Delays the industry fee on sales of brand name pharmaceuticals for use in government health programs by one year to 2011, and increases revenue raised by the fee by \$4.8 billion.



### **About the Author**

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### **About CIS**

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies, from Global Clinical Research & Development through U.S. Commercial Compliance and Government Programs. Founded in 2004 by industry experts, our deep understanding of industry laws and regulations, innovative and practical applications and custom solutions help our clients establish a "Culture of Compliance" that is both meaningful and practical.

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