THE COUNCIL
The Council of Insurance Agents & Brokers

Steptoe

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117th Congress Federal Drug Pricing Legislation

I. Single-Issue Legislation (117th Congress) (*all legislation has been introduced; no further action has been taken, unless noted)*

Drug Pricing Transparency
Prescription Drug Importation
Price Gouging
PBM Reforms and Transparency
Multi-Issue Legislation
Miscellaneous

Drug Pricing Transparency Legislation

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
Lower Costs, More Cures Act H.R. 19 Rep. Cathy McMorris Rodgers (R-WA) House Summary	Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS prior to increasing the price of such drugs, among other things.	In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS); • Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and • Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	*Manufacturers.* Requires manufacturers of qualifying drugs to submit a report to HHS for each price increase that will result in an increase in the wholesale acquisition cost of a drug that is equal to: • 10% or more over a 12-month period; or • 25% or more over a 36-month period. Requires such reports to be submitted to HHS at least 30 days before the planned effective date of the price increase. *HHS.* Requires HHS to submit an annual report to Congress that • Summarizes the information reported by the manufacturer; • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted; • Details the costs and expenditures incurred by HHS in carrying out	Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug.* Requires the report to include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer; • The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current wholesale acquisition cost; • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; and • The total marketing and advertising costs. *Manufacturers.* Requires the report to include: • The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period"); • All stock-based performance metrics used to determine executive compensation during the applicable period; • Any additional information the manufacturer chooses to provide related to its drug pricing decisions (e.g., expenditures on drug R&D, clinical trials of drugs that failed to receive FDA-approval, etc.); and	If a manufacturer fails to submit the requested information, subjects them to a penalty of $75,000 per day for each day that the report is not submitted. Subjects a manufacturer who knowingly provides false information to a penalty of up to $75,000 for each piece of false information in the report.	*Publication of Manufacturer Data.* Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers the day the price increase of a qualifying drug is scheduled to go into effect. *Rebates.* ***Beginning in 2021***, requires HHS to post the aggregate rebates, discounts, and other price concessions achieved by PBMs (e.g., generic dispensing rates) on the CMS website. Requires manufacturers of certain single-dose containers or single-use package drugs under Medicare Part B— excluding new drugs and drugs that require filtration— to provide refunds with respect to discarded amounts of such drugs. Incorporates other transparency requirements, including: • Requires the FTC to conduct a study/provide recommendation to Congress on the role of

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			manufacturer reporting requirements; and • Explains how HHS is improving consumer and provider information about drug value and price transparency.	• Any other information requested by HHS. Requires manufacturers of qualifying drugs to also submit reports to HHS if the estimated cost or spending per individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment.		PBMs and assess potential anticompetitive practices in the drug supply chain; and • Allows certain individuals and entities (e.g., oversight agencies, researchers, private and public healthcare payers, etc.) to request prescription drug marketing sample information from HHS.
Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) Rep. Frank Pallone (D-NJ)	Establishes the Fair Price Negotiation Program ("Program"), limits price hikes for Medicare Part B and D covered drugs, and caps out-of-pocket costs for Medicare Part D enrollees, among other things	All prescription drugs marketed in the U.S. In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS);	*Manufacturers.* Requires manufacturers to report to HHS drug price information for the Program. Requires manufacturers to submit to HHS certain drug pricing information for drugs furnished or dispensed to beneficiaries or participants of group health plans and health insurance offered in the group market. *HHS.* Requires HHS to submit an annual report to Congress that • Summarizes the information reported by the manufacturer; and • Includes copies of the reports/supporting detailed economic	*Manufacturers.* Requires manufacturers of qualifying drugs to submit reports to HHS within 30 days of a price increase that will result in an increase in the wholesale acquisition cost that is equal to: • 10% or more over a 12-month period; or • 25% or more over a 36-month period. Requires manufacturers of qualifying drugs to also submit reports to HHS: • If the estimated price of the qualifying drug or spending per user of such drug is at least $26,000 beginning on or after January 1, 2024; or • There was an increase in the price of the qualifying drug that resulted in an increase in the wholesale acquisition cost that is equal to: – 10% or more within a 12-month period that begins and ends during the 5-year period preceding January 1, 2023; or – 25% or more within a 36-month period that begins and ends during the 5-year period preceding 2023	*Manufacturers.* Subjects a manufacturer of a qualifying drug that fails to submit a required report to a penalty of $75,000 for each day that the report fails to be submitted; and no more than $100,00 for each item of knowingly submitted false information. If a manufacturers charges more than the maximum fair price, subjects manufacturers to a	*Publication of Manufacturer Data.* Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers no later than the day the price increase of a qualifying drug is scheduled to go into effect; and requires HHS to post a list of each manufacturer reported qualifying drug price increase. *Manufacturers*. Establishes a mandatory rebate for manufacturers of all Medicare Part B and Part D drugs for prices that increase more than by inflation (e.g., requires manufacturer pay the price above inflation in a rebate to the Treasury Department).

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		• Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and • Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	analysis that are otherwise submitted. Requires HHS identify and publish a list of 250 negotiation-eligible drugs (e.g., insulin, Medicare Part D drugs, and the top 125 drugs with greatest net spending in the U.S. during the most recent plan year). Requires HHS negotiate drug pricing, for a minimum of 25 drugs, with manufacturers to establish a maximum fair price (e.g., not more than 120% of average international market price (including price averages of Australia, Canada, France, Japan, and U.K.). Requires HHS annually publish a list of the maximum fair prices for each negotiated drug. *DOL*. Imposes annual reporting obligations on DOL with respect to prescription drug prices of drugs furnished to beneficiaries of group health plans.	Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug.* Requires the report to include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer; • The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current wholesale acquisition cost; • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; • The total marketing and advertising costs; • All stock-based performance metrics used by the manufacturer to determine executive compensation; and • Any other information requested by HHS. *Manufacturers.* Requires manufacturers in the negotiation to report to HHS the following information, among other things: • Research and developments costs; • Distribution of sales data and projected future revenue; • Unit costs of production and distribution; • Patent data on existing and pending exclusivity; and • Clinical trial data.	civil monetary penalty. If a manufacturer refuses to enter into negotiations after being selected by HHS, or if the manufacturer leaves the negotiation before a maximum fair price is agreed to, subjects the manufacturer to an escalating excise tax levied on their drug sales during the period of noncompliance.	*Medicare Part D.* ***Beginning in 2024***, caps out-of-pocket costs at $2,000 for Medicare Part D enrollees and incorporates other provisions aimed at modernizing Medicare Part D, including: • Establishing a manufacturer discount program; and • Phasing out the coverage gap discount program to include three phases: deductible, initial coverage, and catastrophic. *DOL*. Requires DOL to report to Congress on rulemaking opportunities to develop: • An agreement process with manufacturers under which manufacturers would provide for inflation rebates being furnished to participants and beneficiaries of group health plans or with coverage offered in the group market); and • Potential models for enforcement mechanisms for such agreement process. In addition to reporting requirements, if the prices of negotiated drugs increase at a percentage higher than the CPI, requires DOL (if feasible) to

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						promulgate regulations to establish an inflation rebate agreement process with manufacturers. Incorporates other provisions, including, among other things: • Appropriates $3 billion to establish and carry out the Fair Price Negotiation Program; • Reduces cost-sharing liability for certain low-income beneficiaries; and • Requires HHS promulgate regulations requiring each direct-to-consumer TV advertisement for a prescription drug include non-misleading information and list prices.