H-3342.1

HOUSE BILL 2363

State of Washington 64th Legislature 2016 Regular Session

By Representatives Cody, Harris, Robinson, Van De Wege, Jinkins, and Tharinger

Read first time 01/11/16. Referred to Committee on Health Care & Wellness.

AN ACT Relating to pharmaceutical drug cost and utilization transparency; amending RCW 43.371.060; and reenacting and amending RCW 43.371.010.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 43.371.010 and 2015 c 246 s 1 are each reenacted and amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Authority" means the health care authority.

(2) "Average wholesale price" means the amount filed with the federal food and drug administration and published in nationally available data books that are utilized by pharmacies, government programs, and third-party payers to determine pricing of drugs in the market.

(3) "Carrier" and "health carrier" have the same meaning as in RCW 48.43.005.

((~~(3)~~)) (4) "Claims data" means the data required by RCW 43.371.030 to be submitted to the database, including billed, allowed and paid amounts, and such additional information as defined by the director in rule.

((~~(4)~~)) (5) "Data supplier" means: (a) A carrier, third-party administrator, or a public program identified in RCW 43.371.030 that provides claims data; and (b) a carrier or any other entity that provides claims data to the database at the request of an employer-sponsored self-funded health plan or Taft-Hartley trust health plan pursuant to RCW 43.371.030(1).

((~~(5)~~)) (6) "Data vendor" means an entity contracted to perform data collection, processing, aggregation, extracts, analytics, and reporting.

((~~(6)~~)) (7) "Database" means the statewide all-payer health care claims database established in RCW 43.371.020.

((~~(7)~~)) (8) "Direct patient identifier" means a data variable that directly identifies an individual, including: Names; telephone numbers; fax numbers; social security number; medical record numbers; health plan beneficiary numbers; account numbers; certificate or license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators; internet protocol address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

((~~(8)~~)) (9) "Director" means the director of financial management.

((~~(9)~~)) (10) "Indirect patient identifier" means a data variable that may identify an individual when combined with other information.

((~~(10)~~)) (11) "Lead organization" means the organization selected under RCW 43.371.020.

((~~(11)~~)) (12) "Office" means the office of financial management.

((~~(12)~~)) (13) "Proprietary financial information" means claims data or reports that disclose or would allow the determination of specific terms of contracts, discounts, or fixed reimbursement arrangements or other specific reimbursement arrangements between an individual health care facility or health care provider, as those terms are defined in RCW 48.43.005, and a specific payer, or internal fee schedule or other internal pricing mechanism of integrated delivery systems owned by a carrier.

((~~(13)~~)) (14) "Unique identifier" means an obfuscated identifier assigned to an individual represented in the database to establish a basis for following the individual longitudinally throughout different payers and encounters in the data without revealing the individual's identity.

Sec. 2. RCW 43.371.060 and 2015 c 246 s 6 are each amended to read as follows:

(1)(a) Under the supervision of and through contract with the office, the lead organization shall prepare health care data reports using the database and the statewide health performance and quality measure set. Prior to the lead organization releasing any health care data reports that use claims data, the lead organization must submit the reports to the office for review.

(b) By October 31st of each year, the lead organization shall submit to the director a list of reports it anticipates producing during the following calendar year. The director may establish a public comment period not to exceed thirty days, and shall submit the list and any comment to the appropriate committees of the legislature for review.

(2)(a) Health care data reports that use claims data prepared by the lead organization for the legislature and the public should promote awareness and transparency in the health care market by reporting on:

(i) Whether providers and health systems deliver efficient, high quality care; ((~~and~~))

(ii) Geographic and other variations in medical care and costs as demonstrated by data available to the lead organization;

(iii) The total amount spent by state and local government entities on the purchase of prescription drugs for employees and dependents, including as a percentage of total amount on medical care;

(iv) A list of the twenty prescription drugs with the highest cost to state and local government in terms of total amount spent and amount spent per prescription, including a comparison of the costs of these twenty prescription drugs to the price paid by the United States department of veterans affairs and the price paid under the 340B drug discount program; and

(v) Annually, and starting the first year claims data from the database is available to produce such a report, trend data over time on the amount spent by medicaid programs, the public employees' benefits board, and city and county governments as measured by claims for classes of prescription drugs, including but not limited to generic, brand name, and specialty drugs. The report must compare costs by pharmaceutical manufacturer and provide profit margin for

the past three years as well as identify the price of such prescription drugs in foreign countries.

(b) Measures in the health care data reports should be stratified by demography, income, language, health status, and geography when feasible with available data to identify disparities in care and successful efforts to reduce disparities.

(c) Comparisons of costs among providers and health care systems must account for differences in the case mix and severity of illness of patients and populations, as appropriate and feasible, and must take into consideration the cost impact of subsidization for uninsured and government-sponsored patients, as well as teaching expenses, when feasible with available data.

(3) The lead organization may not publish any data or health care data reports that:

(a) Directly or indirectly identify individual patients;

(b) Disclose a carrier's proprietary financial information; or

(c) Compare performance in a report generated for the general public that includes any provider in a practice with fewer than four providers.

(4) The lead organization may not release a report that compares and identifies providers, hospitals, or data suppliers unless:

(a) It allows the data supplier, the hospital, or the provider to verify the accuracy of the information submitted to the data vendor, comment on the reasonableness of conclusions reached, and submit to the lead organization and data vendor any corrections of errors with supporting evidence and comments within thirty days of receipt of the report;

(b) It corrects data found to be in error within a reasonable amount of time; and

(c) The report otherwise complies with this chapter.

(5) The office and the lead organization may use claims data to identify and make available information on payers, providers, and facilities, but may not use claims data to recommend or incentivize direct contracting between providers and employers.

(6)(a) The lead organization shall distinguish in advance to the office when it is operating in its capacity as the lead organization and when it is operating in its capacity as a private entity. Where the lead organization acts in its capacity as a private entity, it may only access data pursuant to RCW 43.371.050(4) (c) or (d).

(b) Except as provided in RCW 43.371.050(4), claims or other data that contain direct patient identifiers or proprietary financial information must remain exclusively in the custody of the data vendor and may not be accessed by the lead organization.

(7) The office and the lead organization shall require manufacturers of a pharmaceutical drug that has an average wholesale price of ten thousand dollars or more annually or per course of treatment to file a report pursuant to this section on the component costs for each qualifying drug. The report shall include the following for each drug required in this subsection:

(a) The total costs for the production of the drug including all of the following:

(i) Total research and development costs including but not limited to:

(A) The total costs of any study drug manufactured during this period in support of the federal food and drug administration approved use of the drug;

(B) The total costs of any preclinical studies conducted during this period;

(C) The total costs of any clinical trials conducted during this period;

(D) The total costs associated with the preparation and submission of any regulatory documents submitted to the federal food and drug administration during this period;

(E) Any research and development costs paid by any predecessor in the development of the drug;

(F) The total cost of postapproval clinical studies that are not mandated by the federal food and drug administration;

(G) The total cost of postclinical studies mandated by the federal food and drug administration; and

(H) The total cost of postapproval studies earmarked for publication using external providers of data;

(ii) Total costs for materials, manufacturing, and administration attributable to the drug;

(iii) The total costs paid by any entity other than the manufacturer or predecessor for research and development, including any amount from federal, state, or other governmental programs or any form of subsidies, grants, or other support;

(iv) Any other costs to acquire the drug, including costs for the purchase of patents, licensing, or acquisition of any corporate

entity owning any rights to the drug while in development, or all of these;

(b) The total administrative costs, including marketing and advertising costs for the promotion of the drug;

(c) The total profit as represented in total dollars and a percentage of total company profit derived from the sale of the drug;

(d) The total amount of financial assistance the manufacturer has provided through patient prescription assistance programs if such programs are available, including but not limited to costs associated with direct-to-consumer coupons and amount redeemed;

(e) The average wholesale price of the drug as filed with the federal food and drug administration and for each drug, including a five year history of average wholesale price increases, expressed as a percentage, and including the months each increase took effect and any explanation for the price increase.

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