Ohio Legislative Service Commission

Bill Analysis

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Sub. S.B. 54*

130th General Assembly
(As Reported by H. Health and Aging)

Sens. Kearney and Eklund, Cafaro, Gentile, Smith, Sawyer, Tavares, Schiavoni, Turner, Lehner, Jones, Bacon, Balderson, Beagle, Burke, Coley, Faber, Gardner, Hite, Hughes, LaRose, Manning, Obhof, Oelslager, Patton, Peterson, Schaffer, Seitz, Skindell, Uecker, Widener

BILL SUMMARY

MAMMOGRAMS

- Requires a mammography facility to include certain information in a patient's mammogram summary if the patient's mammogram demonstrates the presence of dense breast tissue.

HEALTH INSURANCE COVERAGE

- Lowers to 26 (from 28) the age to which health insurance coverage must be extended, upon the request of the insured, under certain health policies or plans that provide coverage to an insured's unmarried dependent children.

- Increases to 30 (from 25) the minimum number of hours that an eligible employee works in a normal work week for the purposes of the law governing small employer health benefit plans.

- Specifies that a volunteer firefighter is not an employee for the purposes of the federal Patient Protection and Affordable Care Act.

- Increases the length of one-time, limited duration health insurance policies from not longer than six months to less than 12 months.

* This analysis was prepared before the report of the House Health and Aging Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- Specifies that chemotherapy parity requirements, as they apply to high deductible health plans, apply only after the respective deductible has been met.

CONTROLLED SUBSTANCES

- Requires the State Medical Board to establish, by rule, standards and procedures for physicians to follow in using controlled substances to treat opioid dependence or addiction.

- Modifies the conditions under which buprenorphine is not included in determining whether prescribers have exceeded their limits on personally furnishing controlled substances.

- Requires, beginning April 1, 2015, that certain prescriber-based business entities hold a terminal distributor license from the State Board of Pharmacy in order to possess and distribute buprenorphine-containing drugs used to treat drug dependence or addiction.

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CONTENT AND OPERATION

MAMMOGRAMS

Dense breast tissue notice to patients

Federal law requires a mammography facility to send to each patient who has a mammogram performed there a summary of the written report of the results of the patient's mammogram (see "**Written report to health care providers**," below).[1] The summary must be written in lay terms and sent to the patient not later than 30 days after the mammogram was performed. If the written report's overall final assessment of findings is "suspicious" or "highly suggestive of malignancy," as defined by federal law, the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.[2]

In general, the bill codifies federal law concerning summaries of written mammography reports. In addition, the bill requires a summary to include the following notice if a patient's mammogram demonstrates, based on American College of Radiology Standards, that the patient has dense breast tissue:[3]

> Your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern; rather, it is to raise your awareness and promote discussion with your health care provider regarding the presence of dense breast tissue in addition to other risk factors.

[1] Public Law 102-539. The Mammography Quality Standards Act of 1992 was reauthorized by Congress in 1998 and 2004, with some changes to the law. *See* U.S. Food and Drug Administration, *Radiation-Emitting Products: About Mammography Quality Standards Act (MQSA)* (last updated November 6, 2012), available at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActand Program/AbouttheMammographyProgram/default.htm>.

[2] 21 Code of Federal Regulations (C.F.R.) 900.12(c)(2).

[3] R.C. 3702.40(B).

Written report to health care providers

Federal law requires a mammography facility to (1) prepare a written report of the results of each mammogram performed there and (2) send the report to a patient's health care provider. In general, the report must contain the following information:[4]

(1) The name of the patient and an additional patient identifier;

(2) The date of examination;

(3) The name of the physician who interpreted the mammogram;

(4) An overall final assessment of findings, classified in one of five categories: negative, benign, probably benign, suspicious, or highly suggestive of malignancy;

(5) Recommendations to the health care provider about what additional actions, if any, should be taken.

When a patient has a referring health care provider or the patient has named a health care provider, the facility must send the report to that provider as soon as possible, but not later than 30 days after the mammogram was performed. If an assessment is "suspicious" or "highly suggestive of malignancy," as defined by federal law, the facility must make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.[5]

The bill largely codifies federal law concerning written mammography reports, by requiring a facility to send to the patient's health care provider, if known, a copy of the written report containing the results of the patient's mammogram. The report must be sent not later than 30 days after the mammogram was performed.[6]

Scope of the bill

The bill specifies that its provisions do not create either of the following:[7]

--A new cause of action or substantive legal right against a person, facility, or other entity; or

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[4] 21 C.F.R. 900.12(c)(1).

[5] 21 C.F.R. 900.12(c)(3).

[6] R.C. 3702.40(B).

[7] R.C. 3702.40(C).

--A standard of care, obligation, or duty for a person, facility, or other entity that would provide the basis for a cause of action or substantive legal right, other than the duty to send the summary and written report described above.

Definitions

The bill specifies that the terms, "mammogram" and "facility," have the same meanings as in federal law,[8] which are:

"**Mammogram**" – A radiographic image produced through mammography. ("Mammography" is radiography of the breast.)[9]

"**Facility**" – Any of the following that conducts breast cancer screening or diagnosis through mammography activities: a hospital, outpatient department, clinic, radiology practice, or mobile unit; an office of a physician; or another facility determined by the U.S. Secretary of Health and Human Services. The term does not, however, include a facility of the U.S. Department of Veterans Affairs. ("Mammography activities" include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram, and the viewing conditions for that interpretation.)[10]

HEALTH INSURANCE COVERAGE

Insurance coverage for dependent children

The bill provides that, once an unmarried child has attained the limiting age for dependent children specified in a health insurance policy, contract, agreement, or benefit plan and upon the request of the insured, the health insurer must offer to cover the unmarried child until the child reaches age 26 if certain conditions are satisfied (see "**Limiting age**," below).[11] Current law requires that such coverage extend until the unmarried child reaches age 28; however, it does not require insurers to offer dependent coverage in general.

The insurers subject to these provisions of the bill are health insuring corporations, sickness and accident insurers, multiple employer welfare arrangements, and public employee benefit plans. The provisions do not apply to health insurance that

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[8] R.C. 3702.40(A).

[9] 42 United States Code (U.S.C.) 263b(a)(5) and (6).

[10] 42 U.S.C. 263b(a)(3).

[11] R.C. 1751.14, 3923.24, and 3923.241.

is part of employee benefits offered by private employers that self-insure their benefit programs. These programs are generally precluded from state regulation by the federal Employee Retirement Income Security Act (ERISA) (see "**ERISA**," below).

As noted above, coverage must be extended to an unmarried dependent child upon the request of the insured and if certain conditions are met, including the following: (1) the child is the natural child, stepchild, or adopted child of the insured, (2) the child is an Ohio resident or a full-time student at an accredited public or private institution of higher education, (3) the child is not Medicaid or Medicare eligible, and (4) the child is not employed by an employer that offers any health benefit plan under which the child is eligible for coverage.

Application

These provisions of the bill apply to policies, contracts, agreements, and plans that are delivered, issued for delivery, or renewed in Ohio on or after January 1, 2016.[12]

Limiting age

Existing law allows a health insurance policy or plan offered by a sickness and accident insurer, a health insuring corporation, multiple employer welfare arrangement, or public employee benefit plan that offers coverage for unmarried dependent children to place a "limiting age" on such coverage. Under current law, the attainment of that age may not operate to terminate coverage if the child continues to be both: (1) incapable of self-sustaining employment by reason of mental retardation or physical handicap and (2) primarily dependent on the policyholder for support or maintenance.

Mandated health benefits legislation

The bill's requirements regarding extended coverage for unmarried dependents could be considered mandated health benefits. Under current law, no mandated health benefits legislation enacted by the General Assembly may be applied to any policy, contract, plan, or other arrangement providing sickness and accident or other health benefits until the Superintendent of Insurance determines, pursuant to a hearing conducted in accordance with the Administrative Procedure Act, that the provision can be applied fully and equally in all respects to (1) employee benefit plans subject to regulation by the federal ERISA and (2) employee benefit plans established or modified by the state or its political subdivisions.[13]

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[12] Section 3.

[13] R.C. 3901.71, not in the bill.

The bill includes provisions that exempt its requirements regarding coverage for unmarried dependents from review by the Superintendent. Therefore, the coverage may be implemented without a hearing and a determination that the coverage can be applied to employee benefit plans subject to ERISA.[14]

ERISA

ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

Eligible employees under small employer benefit plans

The bill specifies, for the purposes of the law governing small employer benefit plans, that an eligible employee means an employee who works a normal work week of 30 or more hours. Current law provides that an eligible employee works a normal work week of 25 or more hours. A small employer, in connection with a group health benefit plan, is an employer who employed an average of at least two but no more than 50 eligible employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year.[15] This change conforms Ohio law to provisions in the Patient Protection and Affordable Care Act (ACA) that relate to mandatory health insurance coverage.

Application

These provisions of the bill apply to policies, contracts, agreements, and plans that are delivered, issued for delivery, or renewed in Ohio on or after January 1, 2016.[16]

Volunteer firefighters

With respect to a volunteer firefighter appointed by a municipal corporation or township, the bill provides that the firefighter is a bona fide volunteer and is not a municipal corporation or township employee for the purposes of the federal Patient Protection and Affordable Care Act.[17] The bill specifies that a firefighter is not an

[14] R.C. 1751.14, 3923.24, and 3923.241.

[15] R.C. 3924.01.

[16] Section 3.

[17] R.C. 505.377, 737.082, and 737.222.

employee even if the firefighter or, in some instances, a family member of the firefighter, receives any benefits provided by the following:

(1) The Volunteer Fire Fighters' Dependents Fund;

(2) The Industrial Commission or Bureau of Workers' Compensation;

(3) An annuity program established by a township or municipal corporation for its volunteer firefighters;

(4) A standard liability and casualty insurance policy purchased by a township or municipal corporation for members of its fire department;

(5) The tuition waiver available to a person attending a state-funded college or university who is the child or spouse of a firefighter killed in the line of duty;

(6) A sickness and accident insurance policy that covers a volunteer fire department and its members;

(7) The law that prohibits an employer from terminating an employee who is a volunteer firefighter when that employee is absent from or late to work in order to respond to an emergency prior to the time the employee is to report to work.

One-time, limited-duration policies

The bill increases the length of one-time, limited-duration (OTLD) health insurance policies from not longer than six months to less than 12 months.[18] OTLD policies differ from other health insurance policies in that certain requirements applicable to standard policies do not apply to them. These requirements include the following:

- Uniform prescription drug information on standardized identification cards or other identifying electronic technology;
- Limitations on administrative expenses retained in relation to health policies;
- Coverage of adult dependent children;
- Biologically based mental illness parity;
- Pre-existing conditions coverage;

[18] R.C. 1739.061, 3923.24(E), 3923.241(D), 3923.281, 3923.57, 3923.58, 3923.601, 3923.83, and 3924.01(H).

- Coverage of emergency services;
- Required continuation of coverage;
- Requirements for the discontinuation of insurance products;
- Small employer health benefit plan law requirements.

Chemotherapy parity

Current law requires that orally administered chemotherapy be covered on at least the same basis as intravenously administered or injected cancer medications. The bill specifies that chemotherapy parity requirements, as they apply to high deductible health plans, including catastrophic health plans, apply only after the respective deductible has been met.[19] This change ensures that such plans will be eligible under federal law for health savings accounts (HSA).

Health savings accounts background

An HSA is a tax-exempt savings account that can be used to pay or reimburse certain medical expenses. An HSA can only be set up in relation to certain types of health benefit plans. Federal guidance provided by the Internal Revenue Service (IRS) specifies that high deductible health plans that include prescription drug coverage are eligible for an HSA only if the prescription drug coverage provides no benefits until the deductible is met.[20]

CONTROLLED SUBSTANCES

Physician use of controlled substances to treat dependence or addiction

The bill requires the State Medical Board to establish standards and procedures to be followed by physicians when using schedule III, IV, or V controlled substances to treat opioid dependence or addiction. The bill authorizes the Board to specify the practice type or location in which the standards and procedures are to apply.[21]

The standards and procedures are to be established in rules adopted by the Board in accordance with the Administrative Procedure Act (R.C. Chapter 119.). The

[19] R.C. 1751.69(C) and 3923.85(C)

[20] U.S. Internal Revenue Service. *Health Savings Accounts and Other Tax-Favored Health Plans* (Publication 969), 2013.

[21] R.C. 4731.056.

standards and procedures are applicable to physicians who are medical doctors or osteopathic doctors.

Limits on personally furnishing controlled substances

Under current law, a prescriber (other than a veterinarian) cannot personally furnish more than either of the following:

- 2,500 dosage units in a 30-day period to all patients taken as a whole;
- A 72-hour supply for a patient's use in that period.[22]

Existing law authorizes the State Board of Pharmacy to impose a fine of not more than $5,000 on a prescriber who violates these limits.[23]

Exception for buprenorphine

The bill modifies the conditions under which buprenorphine is not included in determining whether a prescriber has exceeded the limits on personally furnishing controlled substances to patients.[24] Buprenorphine, which is used to treat opioid dependence, prevents withdrawal symptoms when someone stops taking opioid drugs by producing similar effects to the opioid drugs.[25]

Under current law, buprenorphine is excluded from consideration in determining whether the limits have been exceeded if the buprenorphine is provided to treat drug addiction by a prescriber who satisfies federal requirements so as to be exempt from separate registration with the federal Drug Enforcement Administration.[26] The bill replaces this provision with a provision that excludes buprenorphine that is provided to treat drug addiction or dependence as part of an opioid treatment program. For the exclusion to apply, the opioid treatment program must (1) be certified by the federal Substance Abuse and Mental Health Services Administration and (2) must distribute both buprenorphine and methadone.

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[22] R.C. 4729.291(C)(1).

[23] R.C. 4729.291(C)(2).

[24] R.C. 4729.291(D).

[25] U.S. National Library of Medicine, National Institutes of Health, *Buprenorphine Sublingual* (last visited December 2, 2014), available at < http://www.nlm.nih.gov/medlineplus/druginfo/meds/a605002.html>.

[26] R.C. 4729.291(D)(1)(b); *see also* 21 Code of Federal Regulations 1301.28.

Terminal distributor license for prescriber businesses using buprenorphine

Under current law, certain prescriber-based business entities that possess dangerous drugs are exempt from the general requirement to be licensed by the State Board of Pharmacy as terminal distributors of dangerous drugs. For the exemption to apply, each shareholder, member, or partner of the business entity must be authorized to prescribe drugs and authorized to provide the health care professional services offered by the entity.[27]

Beginning April 1, 2015, the bill requires such a business entity to hold a terminal distributor license in circumstances involving buprenorphine. Specifically, the business entity must be licensed in order to possess, have custody or control of, and distribute controlled substances containing buprenorphine that are used for the purpose of treating drug dependence or addiction.[28]

COMMENT

The operation of R.C. 3923.58 was suspended by S.B. 9 of the 130th General Assembly. This section required insurers to offer open enrollment to individuals that could not otherwise obtain insurance. This section was suspended because the open enrollment program was largely subsumed by the federal Patient Protection and Affordable Care Act (PPACA). The bill's amendment of this section does not supersede that suspension.

Because OTLD policies do not have to meet certain requirements, such as the coverage of pre-existing conditions, they may not constitute qualified health plans with regard to the individual mandate enacted in the PPACA. As such, individuals covered by OTLD policies might be subject to the tax penalty associated with the mandate.

HISTORY

ACTION	DATE
Introduced	02-25-13
Reported, S. Medicaid, Health & Human Services	05-14-14
Passed Senate (32-0)	05-28-14
Reported, H. Health & Aging	---

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[27] R.C. 4729.51, not in the bill and 4729.541.

[28] R.C. 4729.541(C)(2).