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Sens. Carnes, Harris, Stivers, Mumper

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ACT SUMMARY

- Modifies the powers and duties of the Director of Health, Department of Health, Public Health Council, and local boards of health relative to the Director's general powers, agreements to sell services or exchange information, investigations, quarantine and isolation, vaccinations and immunizations, the public health laboratory, enforcement of rules and orders, and other public health matters.
- Provides that, during an investigation that the Director is conducting and that is not yet complete, information obtained by the Director is confidential and cannot be released, except under specified conditions.
- Provides that "protected health information" (that is, information that identifies the individual or that could be used to identify the individual) reported to or obtained by the Director, Department, or a local board of health is confidential and cannot be released without the individual's written consent, except under specified circumstances.
- Expands requirements under which specified health care entities must report information to the Department, establishes a criminal penalty for

failure to comply with those requirements, and requires the Director to establish a graduated system of fines based on the scope and severity of violations.

- Requires the Public Health Council to adopt rules related to determining the capacity of trauma centers to respond to disasters, mass casualties, and bioterrorism.

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CONTENT AND OPERATION

Overview and definitions

The act modifies the powers and duties of the Director of Health, the Department of Health, the Public Health Council, and boards of health with specific emphasis on changes that relate to the ability to respond to bioterrorism. The act introduces definitions that are instrumental to these modifications, including the following:

-- "**Bioterrorism**" means the intentional use of any microorganism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of a

microorganism, virus, infectious substance, or biological product, to cause death, disease, or other biological malfunction in a human, animal, plant, or other living organism as a means of influencing the conduct of government or intimidating or coercing a population (R.C. 3701.232(A)(1)).

--"**Protected health information**" means information, in any form, including oral, written, electronic, visual, pictorial, or physical that describes an individual's past, present, or future physical or mental health status or condition, receipt of treatment or care, or purchase of health products, if either of the following applies:

(1) The information reveals the identity of the individual who is the subject of the information.

(2) The information could be used to reveal the identity of the individual who is the subject of the information, either by using the information alone or with other information that is available to the predictable recipients of the information. (R.C. 3701.17(A)(2).)

--"**Surveillance**" in the public health service means the systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community in order to control and prevent disease in the community (R.C. 3701.072(A)(2)).

General powers of the Director of Health

(R.C. 3701.03)

Under continuing law, the Director of Health, as chief executive officer of the Department of Health, is charged with administering health and sanitation laws and Department rules. Under the act, the Director may designate employees of the Department and, during a public health emergency, other persons to administer the laws and rules on the Director's behalf.

The act limits the actions the Director may take by specifying that this authority does not permit any action that prevents the fulfillment of duties or impairs the exercise of authority established by law for any other person or entity.

Agreements to sell services or exchange information

(R.C. 3701.04(B))

Continuing law authorizes the Director of Health to enter into agreements to sell Department of Health services to other departments, agencies, and

institutions of the state. The act specifies that under this authority the Director may enter into agreements to sell services to boards of health of city and general health districts. In addition, the act expands the Director's authority by permitting the Director to enter into agreements to sell Department services to other states and the United States.

Investigations; confidentiality of information

(R.C. 3701.14)

Continuing law requires the Director of Health to inquire into the cause of disease, especially when contagious, infectious, epidemic, or endemic, and take prompt action to control and suppress the disease. The act expands the provision by requiring the Director to make inquiry "or investigate" the cause of disease "or illness," including pandemic conditions. The act stipulates that information obtained during any investigation or inquiry that is not yet complete is confidential during the course of that investigation or inquiry and cannot be released *except* under one of the following conditions:

(1) The confidential information is released pursuant to a search warrant or subpoena issued by or at the request of a grand jury or prosecutor.

(2) The Director enters into a written agreement to share or exchange the information with a person or government entity and that agreement requires the person or entity to comply with the act's confidentiality requirements.

(3) The information is contained in a preliminary report released by the Director pursuant to the act (see below).

Information disclosed under (1) or (2), above, must be in writing and accompanied by a written statement that includes the following or substantially similar language: "This information has been disclosed to you from confidential records protected from disclosure by state law. If this information has been released to you in other than a summary, statistical, or aggregate form, you shall make no further disclosure of this information without the specific, written, and informed release of the person to whom it pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for the release of information pursuant to this section."

As suggested by this mandatory statement, the act's confidentiality requirements do not bar the release of information that is in summary, statistical, or aggregate form and that does not identify a person: such information is a public document under the Ohio Open Records Law. Additionally, the act *requires* the Director to release information obtained during an investigation or inquiry that is

not yet complete *if* the Director determines the release of the information is necessary, based on an evaluation of relevant information, to avert or mitigate a clear threat to an individual or to the public health. Release of that information is limited to those persons necessary to control, prevent, or mitigate disease or illness.

With the exception of "protected health information," which is governed by the provision of the act that specifically addresses that type of information, these confidentiality requirements apply during *any* investigation or inquiry the Director makes with respect to disease, illness, or health conditions, notwithstanding any other provision of the Revised Code that establishes the manner of maintaining confidentiality or the release of information.

If an investigation or inquiry is not completed within six months after the date of commencement, the Director is required by the act to prepare and release a report containing preliminary findings. A supplementary preliminary report must be prepared every six months thereafter. Upon completion of any investigation or inquiry, the Director is to prepare and release a final report. None of the reports, however, can contain protected health information. The act requires the Director to adopt, in accordance with the Administrative Procedure Act, rules establishing the manner in which these reports are to be released.

The act states that the Director's authority to investigate disease, illness, and health conditions does not authorize the Director to conduct an independent criminal investigation without the consent of each local law enforcement agency with jurisdiction to conduct the criminal investigation.

Quarantine and isolation; emergency actions by a health commissioner

(R.C. 3701.13 and 3707.34)

Prior law granted the Department of Health "supreme authority" in matters of quarantine, which it could declare, modify, or abolish. Under the act, this authority is changed to "ultimate" authority and is also granted in matters of "isolation," which the Department likewise may declare, modify, or abolish. The act requires that, whenever possible, the Department work in cooperation with the health commissioner of a general or city health district.

In enforcing the law on quarantine and isolation, the act authorizes the health commissioner appointed by a board of health of a general or city health district to act on behalf of the board if (1) circumstances make a meeting of the board impractical or impossible or (2) delaying action until a meeting of the board compromises the public health. The act directs each board of health to adopt a policy, subject to the approval of the district advisory council (or the city council

for city health districts not governed by an advisory council), specifying the actions that a health commissioner may take on behalf of the board. Any action a health commissioner takes in accordance with the board's policy is considered an action taken by the board unless the board votes to nullify the commissioner's action.

Vaccinations and immunizations; other pharmaceutical agents

(R.C. 3701.13 and 3701.16)

Under continuing law, the Department of Health may approve means of immunization against diphtheria, rubella, tetanus, hepatitis B, and other specified diseases. The act adds "mumps" to the list of specified diseases, and allows the Department also to take actions necessary to encourage vaccination against any of the diseases.

The act authorizes the Director of Health to purchase, store, and distribute antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies the Director deems advisable in the interest of preparing for or responding to a public health emergency. The act stipulates that this *discretion* related to antibiotics and other agents and supplies does not relieve the Director of the *duty* under continuing law to make necessary arrangements for the production and distribution of diphtheria antitoxin.

Public health laboratory

(R.C. 3701.15 and 3701.22)

The Department of Health formerly was required to maintain a "chemical and bacteriological" laboratory for the examination of public water supplies, diagnosis of diseases, and analysis of patient specimens and food samples. The act modifies this requirement to:

(1) Refer to the laboratory as a "public health" laboratory rather than a "chemical and bacteriological" laboratory;

(2) Expand the duties of the laboratory to include the diagnosis of, screening for, or confirmation of diseases or pathogens and the performance of biological, chemical, or radiological analyses or examinations as the Department deems necessary.

Duties of the Public Health Council

(R.C. 3701.06, 3701.34, 3701.35, and 3701.56)

Under prior law, the Public Health Council was required to take evidence in appeals from the Director of Health's decisions in a matter that related to the approval or disapproval of plans, locations, estimates of cost, or other matters coming before the Director for official action. The act removes this requirement.

Prior law also required the Public Health Council to adopt sanitary rules for general application throughout Ohio, to be known as the "Sanitary Code." The act removes references to the Sanitary Code and instead refers generally to "rules."

Enforcement of rules and orders; violations

(R.C. 3701.352, 3701.56, and 3701.99)

Prior law delegated the enforcement of the Department's "quarantine and sanitary rules" to boards of health of a general or city health district, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and other officers and employees of the state or any county, city, or township. Under the act, these entities and individuals must enforce any of the Department's rules and also any quarantine and isolation orders.

Ongoing law prohibits the violation of any rule of the Public Health Council or any order the Director of Health issues under Department of Health Law (R.C. Chapter 3701.). The act expands the prohibition to include violations of: (1) rules the Director or Department adopts and (2) orders the Director or Department issues under the Department of Health Law "to prevent a threat to the public caused by a pandemic, epidemic, or bioterrorism event."

Formerly, a violation of Public Health Council rules or the Director's orders was a minor misdemeanor on a first offense and a misdemeanor of the fourth degree on each subsequent offense. Under the act, a violation of the modified prohibition is a misdemeanor of the second degree.

Protected health information and confidentiality requirements

(R.C. 3701.17)

Under the act, "protected health information" reported to or obtained by the Director of Health, the Department of Health, or a board of health of a city or general health district is confidential and cannot be released without the written consent of the individual who is the subject of the information, unless one of the following applies:



(1) The release of the information is necessary to provide treatment to the individual and the information is released pursuant to a written agreement that requires the recipient of the information to comply with the act's confidentiality requirements.

(2) The release of the information is necessary to ensure the accuracy of the information and the information is released pursuant to a written agreement that requires the recipient of the information to comply with the act's confidentiality requirements.

(3) The information is released pursuant to a search warrant or subpoena issued by or at the request of a grand jury or prosecutor in connection with a criminal investigation or prosecution.

(4) The Director determines the release of the information is necessary, based on an evaluation of relevant information, to avert or mitigate a clear threat to an individual or to the public health. Information may be released pursuant to this provision only to those persons or entities necessary to control, prevent, or mitigate disease.

The act specifies that information that does not identify an individual is not protected health information and may be released in summary, statistical, or aggregate form. Such information is a public document under the Ohio Open Records Law and must be released by the Director, upon request.

The act also requires that, except for information released pursuant to (4) above, any disclosure must be in writing and accompanied by a written statement that includes the following or substantially similar language: "This information has been disclosed to you from confidential records protected from disclosure by state law. If this information has been released to you in other than a summary, statistical, or aggregate form, you shall make no further disclosure of this information without the specific, written, and informed release of the individual to whom it pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for the release of information pursuant to this section."

In addition to providing these general requirements regarding confidentiality of protected health information, the act specifically applies them to information that is released by a hospital or dispensary (R.C. 3701.07(A)), when specified diseases are reported by boards of health, health authorities or officials, health care providers in localities in which there are no health authorities or officials, and coroners or medical examiners (R.C. 3701.23(E)), when pharmacies and pharmacists report information (R.C. 3701.232(D)), when physicians report

occupational illnesses (R.C. 3701.25(E)), and when physicians, building owners, and heads of families report specified illnesses (R.C. 3707.06(C)).

Reporting requirements

Trauma centers

(R.C. 149.43 and 3701.072)

The act requires the Public Health Council to adopt rules, in accordance with the Administrative Procedure Act, that require a trauma center to report information to the Director of Health describing the trauma center's preparedness and capacity to respond to disasters, mass casualties, and bioterrorism. The rules may require the reporting of any information the Council considers necessary for an accurate description of a trauma center's preparedness and capacity to respond to disasters, mass casualties, and bioterrorism. Information that a trauma center reports is not a public record under the Ohio Public Records Law.

Following a required review of the information that trauma centers provide, the Director may conduct an evaluation of a trauma center's preparedness and capacity to respond to disasters, mass casualties, and bioterrorism. The evaluation is not a public record under the Ohio Public Records Law. The act also requires that, upon request, the Department of Health provide a summary report of the Council's rules related to trauma centers.

"Trauma center" has the same meaning as in the Division of Emergency Medical Services Law (R.C. Chapter 4765.).

Health care providers

(R.C. 3701.23 and 3701.24(B))

Under continuing law, boards of health, health authorities or officials, and physicians in localities in which there are no health authorities or officials, must promptly report to the Department of Health the existence of specified contagious or infectious diseases. The act expands the application of this requirement to "health care providers" (rather than physicians) in localities in which there are no health authorities or officials and to coroners and medical examiners. In addition, it requires the reporting of other illnesses, health conditions, or unusual infectious agents or biological toxins posing a risk of human fatality or disability, as specified by the Public Health Council. These reports are to be submitted on forms, as required by statute or rule, and in the manner the Director prescribes.

For purposes of the act, **"health care provider"** is defined as any person or government entity that provides health care services to individuals.

Out-of-state medical laboratories

(R.C. 3701.231)

Under the act, if a medical laboratory outside Ohio performs a test or other diagnostic or investigative analysis that results in information pertaining to an Ohio resident that must be reported by a health care provider, building owner, or head of family under Ohio law, the entity using the laboratory must ensure that the laboratory complies with the applicable reporting and confidentiality requirements and verify its compliance to the Director pursuant to procedures the Director establishes.

Pharmacies and pharmacists

(R.C. 3701.232)

The act authorizes the Public Health Council to adopt rules, in accordance with the Administrative Procedure Act, that require a pharmacy or pharmacist to report significant changes in medication usage that may be caused by bioterrorism, epidemic or pandemic disease, or established or novel infectious agents or biological toxins posing a risk of human fatality or disability. Events that may have to be reported include the following:

- (1) An unexpected increase in the number of prescriptions for antibiotics;
- (2) An unexpected increase in the number of prescriptions for medication to treat fever or respiratory or gastrointestinal complaints;
- (3) An unexpected increase in sales of, or the number of requests for information on, over-the-counter medication to treat fever or respiratory or gastrointestinal complaints;
- (4) Any prescription for medication used to treat a disease that is relatively uncommon and may have been caused by bioterrorism.

Poison prevention and treatment centers; other health-related entities

(R.C. 3701.19 and 3701.201)

The act requires the Public Health Council to adopt rules, in accordance with the Administrative Procedure Act, under which a poison prevention and treatment center or other health-related entity is required to report events that may be caused by bioterrorism, epidemic or pandemic disease, or established or novel infectious agents or biological or chemical toxins posing a risk of human fatality or disability. Events that rules may have to be reported include the following:

(1) An unexpected pattern or increase in the number of telephone inquiries or requests to provide information about poison prevention and treatment and available services;

(2) An unexpected pattern or increase in the number of requests to provide specialized treatment, consultation, information, and educational programs to health care professionals and the public;

(3) An unexpected pattern or increase in the number of requests for information on established or novel infectious agents or biological or chemical toxins posing a risk of human fatality or disability that is relatively uncommon and may have been caused by bioterrorism.

The act requires each poison prevention and treatment center and other health-related entity to comply with any reporting requirement established in rules adopted under this provision.

Failure to comply with reporting requirements: penalties and fines

(R.C. 3701.23(C), 3701.232(C), 3701.24(C), 3701.25(B), 3701.571, 3701.99(A), 3707.06(B), and 3707.99)

The act prohibits any person from failing to comply with the reporting requirements applicable to boards of health, health authorities or officials, health care providers in localities in which there are no health authorities or officials, coroners and medical examiners, pharmacies and pharmacists, persons designated by Public Health Council rules to report certain AIDS related information, and physicians attending a patient suffering from specified occupational diseases. A violation of this prohibition is a minor misdemeanor on a first offense and a misdemeanor of the fourth degree on each subsequent offense.

The act also prohibits any physician or other person attending persons suffering from cholera, plague, yellow fever, typhus fever, diphtheria, typhoid fever, or any other disease dangerous to the public health, from failing to comply with a requirement of continuing law to report certain information to the health commissioner in the jurisdiction where the sick person is found. This reporting requirement, and the act's prohibition against failure to comply with the requirement, also apply to the owner of the building in which the sick person resides and the head of the sick person's family. A violation of this prohibition is a minor misdemeanor on a first offense and a misdemeanor of the fourth degree on each subsequent offense.

The act requires the Director of Health to adopt rules pursuant to the Administrative Procedure Act that establish a graduated system of fines based on



the scope and severity of violations and the history of compliance, not to exceed \$750 per incident, and permits the Director, in an adjudication under the Administrative Procedure Act, to impose a fine against any person who fails to comply with the act's reporting requirements. The Director also may impose a fine against any poison prevention and treatment center or other health-related entity that fails to comply with the act's reporting requirement for those entities. On request of the Director, the Attorney General must bring and prosecute to judgment a civil action to collect any fine imposed under this provision that remains unpaid. All fines collected are to be deposited into the state treasury to the credit of the Department's General Operations Fund. (Other fines the Department of Health collects for specified violations, including violations of any orders or rules of the Department, will continue to be paid into the General Revenue Fund (R.C. 3701.57).)

Other provisions: renumbering and conforming changes

(R.C. 339.89, 3701.04(A)(5), 3701.14(B), 3701.146, 3701.161, 3701.162, 3701.221, 3701.241, 3701.501, 3701.99(E), 3707.38, 3715.02, 3901.46, and 4736.01)

The act relocates (from R.C. 3701.14(B) to 3701.146) the ongoing provisions regarding actions the Director of Health and Public Health Council take with respect to tuberculosis. In addition, the act renumbers several sections, makes corrections, and makes other conforming changes necessitated by its provisions.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	01-23-03	p. 73
Reported, H. Homeland Security, Engineering, & Architectural Design	06-25-03	p. 963
Passed House (98-1)	06-25-03	pp. 974-975
Reported, S. Finance & Financial Institutions	10-15-03	p. 1098
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House concurred in Senate amendments (89-2)	10-15-03	pp. 1125-1127

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