

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 992

INTRODUCER: Senator Bean

SUBJECT: Infectious Disease Control

DATE: March 26, 2014

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Peterson</u>	<u>Stovall</u>	<u>HP</u>	<u>Pre-meeting</u>
2.	_____	_____	<u>AHS</u>	_____
3.	_____	_____	<u>AP</u>	_____

I. Summary:

SB 992 revises the duties of the Department of Health (DOH) to direct specific attention to treatment-resistant bacterial infections. Specifically, the bill directs the DOH to:

- Create a public website where physicians and nurses may report confirmed infections.
- Establish a research panel to make recommendations to other state agencies related to biomedical research programs to improve treatment outcomes and protocols to control treatment-resistant bacterial infections.
- Establish a lead agency task force to identify response protocols for licensed health care facilities in the event of an outbreak and to establish a volunteer emergency response team to investigate and report outbreaks.

II. Present Situation:

Antibiotic Resistance

Antibiotic resistance is a natural phenomenon that occurs when an antibiotic has lost its ability to effectively control or kill bacterial growth. When an antibiotic is used, bacteria which can resist that antibiotic have a greater chance of survival than those that are “susceptible.” When susceptible bacteria are killed or inhibited by an antibiotic, this creates selective pressure for the resistant strains to survive.¹ Some resistance occurs naturally. But the increasingly higher-levels now occurring are the result of the overuse and misuse of antibiotics both by humans, most commonly when prescribed to treat a viral infection or prescribed in the wrong dose or for the incorrect amount of time, and in livestock production to promote growth.²

¹ Alliance for the Prudent Use of Antibiotics, *General Background: About Antibiotic Resistance*, http://www.tufts.edu/med/apua/about_issue/about_antibioticres.shtml (last visited Mar. 27, 2014).

² Alliance for the Prudent Use of Antibiotics, *General Background: What can be done about Antibiotic Resistance?*, http://www.tufts.edu/med/apua/about_issue/what_can_be_done.shtml (last visited Mar. 27, 2014).

The Centers for Disease Control and Prevention (CDC) estimates that more than 2 million people become ill each year due to antibiotic-resistant infections, resulting in the death of at least 23,000. *Clostridium difficile* (*C.diff.*) infections are not yet drug resistant, but most are directly related to antibiotic use. These infections result in an estimated additional 250,000 hospitalizations.³

In most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional physician visits, and result in greater disability and death than treatable infections. The total economic cost of antibiotic resistance to the U.S. economy has been estimated as high as \$20 billion in health care system costs, and \$35 billion in societal costs resulting from lost productivity.⁴

In a report released in 2013, the CDC prioritized the threat posed by bacteria into three categories: urgent, serious, and concerning. The threat was assessed according to seven factors associated with resistant infections:⁵

- Clinical impact
- Economic impact
- 10-year projection of incidence
- Transmissibility
- Availability of effective antibiotics
- Barriers to transmission

The threat analysis resulted in a priority list of 17 bacteria and one fungus: three urgent threats; 12 serious threats; and three concerning threats.⁶

To combat the threats, the CDC has recommended a four-part strategy of prevention, tracking, improving antibiotic use, and developing more resistant antibiotics.⁷ The President's budget request for the 2015 fiscal year includes \$30 million, the first year of a 5-year funding plan, to fund the strategy. The Detect and Protect Against Antibiotic Resistance initiative targets five of the bacteria on the threat list: *C.diff.*, CRE, MRSA, and drug resistant *Pseudomonas*, drug resistant *Salmonella*—with targeted reductions in associated infections of up to 50 percent.⁸

³ Centers for Disease Control and Prevention, *Antibiotic Resistant Threats in the United States, 2013*, 11 (Sept. 2013), available at

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&sqi=2&ved=0CCYQFjAA&url=http%3A%2F%2Fwww.cdc.gov%2Fdrugresistance%2Fthreat-report-2013%2Fpdf%2Far-threats-2013-508.pdf&ei=I0o0U5qAH6jA0OG5zYG0BQ&usq=AFQjCNHv-BZapjIjn8KobhkrFT3ngVUtXg> (last visited March 27, 2014). Due to limitations in available research, the numbers used by the CDC are approximations which underestimate the actual impact of the infections. Centers for Disease Control and Prevention, *Antibiotic Resistant Threats in the United States, 2013*, 18.

⁴ *Id.* at 11.

⁵ *Id.* at 20.

⁶ *Id.* at 7.

⁷ Centers for Disease Control, CDC Newsroom, *Untreatable: Report by CDC details today's drug-resistant health threats*, (Sept. 16, 2013), <http://www.cdc.gov/media/releases/2013/p0916-untreatable.html> (last visited March 27, 2014).

⁸ Centers for Disease Control and Prevention, *CDC—Detect and Protect Against Antibiotic Resistance*, available at <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCYQFjAA&url=http%3A%2F%2Fwww.cdc.gov%2Ffmo%2Ftopic%2Fbudget%2520information%2FFY-2015-Fact-Sheets%2FDetect-and-Protect-Against-Antibiotic-Resistance.pdf&ei=XFc0U9iKPOjjsASqm4HwBQ&usq=AFQjCNFz-uyFsgpL6Db3jGW951Xv2mWWVA> (last visited Mar. 27, 2014).

Communicable Diseases

The DOH is responsible for implementing a communicable disease⁹ prevention and control program.¹⁰ It has broad authority to adopt rules for the prevention and control of communicable diseases, including procedures for investigation, timeframes for reporting, definitions, procedures for managing, required follow up related to suspected exposures, and procedures for providing access to confidential information.¹¹

The DOH is also granted authority to conduct epidemiological studies of diseases of public health significance.¹² The rules implementing this function are set forth in Rule 64D-3, F.A.C. In general, the DOH rules require physicians, chiropractors, naturopaths, nurses, midwives, veterinarians, and medical examiners who treat or suspect a case or occurrence of a notifiable disease or condition to report to the DOH.¹³ Likewise, a laboratory must report to the DOH when a test suggests or diagnoses a notifiable disease or condition.¹⁴ Information submitted in reports is confidential and exempt from the public records laws and may be disclosed only when necessary to public health.¹⁵

The DOH rule contains a Table of Notifiable Diseases and Conditions, which specifies reporting timeframes by disease or condition type and covers an extensive list of specific diseases, including when a case, cluster of cases, or outbreak of a disease or condition found in the general population or an institution is of urgent public health significance.^{16,17} The list is based on the notifiable diseases recommended by the Council of State and Territorial Epidemiologists¹⁸ and the CDC, but may be expanded by the DOH.¹⁹ Currently the table includes five of the 18 threats identified by the CDC in its 2013 report.²⁰ The DOH has initiated rulemaking to add four additional bacteria²¹ that appear on the CDC threat list and to require laboratories to report drug resistant tuberculosis bacteria, which also appears as a threat on the CDC list.²² As part of its

⁹ “Communicable disease” is defined as any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indicated. (s. 381.003(1), F.S.; *See, also* Rule 64D-3.028, F.A.C.) Communicable diseases include all infectious diseases, as well as diseases such as botulism, ricin intoxication and saxitoxin. These three are examples of communicable, but not infectious, diseases now reportable in Florida. (Fla. Dept. of Health, *Senate Bill 992 Bill Analysis* (Jan. 23, 2014) (on file with the Senate Health Policy Committee).

¹⁰ Section 381.003(1), F.S.

¹¹ Section 381.003(8), F.S.

¹² Section 381.0031(1), F.S.

¹³ Rule 64D-3.030, F.A.C.

¹⁴ Rule 64D-3.030, F.A.C.

¹⁵ Section 381.0031(6), F.S.

¹⁶ Rule 64D-3.029(3), F.A.C.

¹⁷ “Urgent public health significance” is a characteristic of a disease or condition that requires rapid public health response due to the potential to cause significant morbidity or mortality; potential to spread between or to humans; and the number of cases. (Rule 64D-3.028(28), F.A.C.)

¹⁸ The list is available at: <http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/CSTENotifiableConditionListA.pdf> (last visited Mar. 27, 2014).

¹⁹ Section 381.0031(\$), F.S.

²⁰ MRSA, multi-drug resistant Gonnorrhoea, VRSA, and *Streptococcus pneumoniae*.

²¹ Carbapenem-resistant enterobacteriaceae, ESBLs, VRE, and Acinetobacter.

²² E-mail from Marco T. Paredes, Jr., Director, Office of Legislative Planning, Fla. Dept. of Health (Mar. 28, 2014) (on file with the Senate Committee on Health Policy).

surveillance program, the DOH produces weekly tables and annual summaries that include data summaries of antimicrobial resistance of the organisms under surveillance and makes these data available to the public on an internet website.²³

The DOH, in coordination with the county health departments, conducts activities to prevent and control diseases of public health significance. The DOH has epidemiologists, statisticians, and clinicians who utilize the data reported under the surveillance program to investigate disease cases and outbreaks; document outbreaks; and make infection control recommendations to control the spread of disease. The DOH also has emergency response teams to control disease outbreaks and processes and protocols that integrate with existing systems for reporting to the CDC.²⁴

The State Surgeon General has specific responsibility for declaring public health emergencies and issuing public health advisories.²⁵ Before issuing an advisory, the State Surgeon General must consult with affected state agencies or local governments regarding areas of responsibility.²⁶ A public health emergency is an occurrence or threat that results or may result in substantial injury or harm to the public from infectious disease, among other agents and events.²⁷ Before declaring a public health emergency, the Surgeon General must consult with the Governor and the Chief of Domestic Security.²⁸

Infection Reporting and Prevention Initiatives

As a condition of receiving payment, hospitals participating in the Medicare program are now required to report to the CDC's National Health Safety Network regarding certain hospital acquired infections. Infections that must be reported currently include: central line-associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, and two of the infections appearing on the CDC threat list, MRSA Bacteremia, and *C.diff*.²⁹ This information is posted on the Hospital Compare website, which allows consumers to compare hospital performance on specific quality of care indicators.³⁰

In addition, current law requires hospitals to report data about infections to the Agency for Health Care Administration.³¹ To implement the requirement, the Agency for Health Care Administration is obtaining the data reported to the CDC and republishing it on

²³ Fla. Dept. of Health, *supra* note 11. See <http://www.floridacharts.com/merlin/freqrpt.asp> (last visited Mar. 27, 2014).

²⁴ *Id.*

²⁵ Section 381.00315, F.S.

²⁶ Section 381.00315(1)(a), F.S.

²⁷ Section 381.00315(1)(b), F.S.

²⁸ *Id.*

²⁹ Medicare.gov Hospital Compare, *Healthcare-associated infections*, <http://www.medicare.gov/hospitalcompare/Data/Healthcare-Associated-Infections.html?AspxAutoDetectCookieSupport=1> (last visited Mar. 28, 2014).

³⁰ Medicare.gov Hospital Compare, *What Is Hospital Compare?*, <http://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html> (last visited Mar. 28, 2014).

³¹ Section 408.0361(5)(a)2., F.S.

HealthFinder.gov, which is Florida's publicly-accessible, health care facility comparison website.³²

III. Effect of Proposed Changes:

SB 992 revises the duties of the DOH with respect to control of diseases and related coordination with federal, state, and local officials, to substitute the word "infectious" for "communicable." The bill directs the DOH to create a website for reporting by physicians and nurses of confirmed treatment-resistant bacterial infections. The website must require the practitioner to enter his or her license number and the location and type of infection. The DOH is directed to adopt rules to ensure that only one report per confirmed case is posted on the website and to protect the identity of the reporting practitioner and the confidentiality of protected health information.

The bill directs the DOH to establish a panel composed of experts in the field of treatment-resistant bacterial infections to make recommendations to state agencies regarding biomedical research programs to improve treatment outcomes and develop protocols to control the incidence of treatment resistant infections.

The bill directs the DOH to establish and lead an interagency task force that includes representatives from health care providers, interested trade associations, and other state agencies to:

- Identify emergency response protocols for health care facilities in the event of an outbreak in the facility; and,
- Establish a volunteer statewide emergency response team to investigate, document, and report the presence and outbreak of a treatment-resistant bacterial infection to the DOH and the CDC.

The bill has an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

³² E-mail from Joshua Spagnola, Legislative Affairs Director, Agency for Health Care Administration (March 28, 2014) (on file with the Senate Committee on Health Policy).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians and nurses who report to the website will incur an indeterminate cost for the time required to submit the report.

C. Government Sector Impact:

Estimated Expenditures	Year 1	Year 2
Salaries		
1 Senior Epidemiologist @ \$60,662 (pay grade 550)	\$ 61,420	\$ 81,893
1 Biological Scientist IV @ \$43,507 (pay grade 25)	44,051	58,735
1 Operations Analyst II @ \$30,989 (pay grade 19)	31,376	41,835
FTE computed with 35% fringe and 25% lapse for year 1		
Expenses		
2 FTE (Standard professional package with medium travel @ \$19,579 includes computing equipment)	39,158	31,634
2 FTE (Standard professional package with limited travel @ \$16,021 includes computing equipment)	32,042	23,558
HR Statewide Contract @ \$354	1,416	1,416
Travel for Research Panel	5,000	10,000
Travel for Task Force Members	10,000	15,000
Travel for Volunteer Emergency Responders	10,000	15,000
Meeting Room Rental	6,000	8,000
Printing	2,500	3,500
Meeting Notice	500	800
Contracts		
Website Development and Maintenance:		
1 Project Manager 1,900 hours @ \$110 per hour	209,000	110,000
2 Developers for 1,900 hours @ \$90 per hour	342,000	
1.25 Developers Recurring 2,375 hours		213,750
1 Tester 1,000 hours @ \$75 per hour	75,000	75,000
TOTAL	\$869,463	\$690,121

VI. Technical Deficiencies:

The requirement to establish a website and related process for health care practitioners to report cases of resistant bacterial infections seems to be inconsistent with or duplicative of the reporting process already established in s. 381.0031, F.S.

Reports submitted under current law are exempt from public records disclosure; whereas, reports submitted to the new website may not be.

By changing the term “communicable disease” to “infectious disease,” the bill may conflict with ss. 381.003 and 381.0031, F.S. Other terms, such as “treatment-resistant bacterial infection,” “location of infection,” and “confirmed treatment-resistant bacterial infection” are vague and may need to be defined or further clarified.

Some provisions, in particular related to research, may be difficult to implement without further detail, a specific grant of authority related to the DOH or another agency to conduct the research, and a related appropriation.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0011 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.