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:	CS/SB 992
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Infectious Disease Control
DATE:	April 2, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 992 directs the Department of Health (DOH) to convene a study group of affected stakeholders to assess the efficacy of the state's current system of surveillance, reporting, public notification, prevention, and response activities related to antibiotic-resistant bacteria. The bill requires the study group to submit a report of its findings, an action plan for implementation, and recommendations for necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.

The bill also updates a reference in statute to the pneumococcal vaccine that is provided to nursing home residents upon admission.

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]

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]

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[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).
[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=I0o0U5qAH6jA0QG5zYGQBQ&usg=AFQjCNHv-BZapjIjn8KobhkrFT3ngVUtXg* (last visited Mar. 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.

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]

Communicable Diseases

The DOH is responsible for implementing a communicable disease[9] 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

[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&usg=AFQjCNFz-uyFsgpL6Db3jGW951Xv2mWWVA (last visited Mar. 27, 2014).
[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.

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 Epidemiologists[18] 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 bacteria[21] 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 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 State 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

[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 Gonnorrhea, VRSA, and *Streptococcus pneumonia*.
[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).
[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.*

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 (AHCA).[31]To implement the requirement, the AHCA is obtaining the data reported to the CDC and republishing it on HealthFinder.gov, which is Florida's publicly-accessible, health care facility comparison website.[32]

Pneumococcal Disease

Pneumococcal disease causes meningitis, bloodstream infections, and pneumonia. As many as 175,000 people are hospitalized due to pneumococcal pneumonia in the U.S. annually. In its worst form, the disease kills one in every four to five people over the age of 65 who contract it.[33]

In 1997, the CDC's Advisory Committee on Immunization Practices revised its recommendations for the use of pneumococcal vaccine, calling for vaccination of certain high risk groups, including persons over the age of 65.[34] There are two types of pneumococcal vaccines available for adults: a pneumococcal polysaccharide vaccine (PPSV23) and a pneumococcal conjugate vaccine (PCV13).[35]

Section 400.141, F.S., requires nursing homes to assess a resident's eligibility for vaccination against pneumococcal disease within 5 days after admission, but only references the pneumococcal polysaccharide vaccine.

III. Effect of Proposed Changes:

CS/SB 992 directs the DOH to convene a study group to assess the efficacy of state surveillance, mandatory reporting, public notification, prevention, and response activities related to antibiotic-resistant bacteria.

The study group must include representatives of facilities licensed under ch. 395, F.S. (hospitals, ambulatory surgical centers, and mobile surgical facilities), ch. 400, F.S. (nursing homes and related health care facilities), part I of ch. 483, F.S. (clinical laboratories), physicians, nurses,

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[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.
[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).
[33] National Foundation for Infectious Disease, *Pneumococcal Disease*, http://www.adultvaccination.com/pneumococcal_vaccine_vaccination_adult_immunization.htm (last visited April 2, 2014).
[34] Centers for Disease Control and Prevention, Office of Enterprise Communication, *CDC Recommends Pneumococcal Vaccination For All Senior Citizens and Others at High Risk* (May 1997), http://www.cdc.gov/media/pressrel/pneumovx.htm (last visited April 2, 2014).
[35] *Supra* note 33.

veterinarians, the AHCA, and the DOH. At least two members must be certified infection control practitioners. The DOH is authorized to reimburse travel.

The study group is directed to evaluate what types of bacteria are currently reported and how; how information is distributed to the public; the coordination of response activities between state and federal agencies, local government, school boards, affected facilities, and the public; and any other issues the study group determines are necessary and appropriate.

The study group must submit a report of its findings, an action plan for implementation, and recommendations for any necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.

In addition the bill changes the reference to the pneumococcal vaccine that must be provided to nursing home patients upon admission. The current law references one of two vaccination types that are currently recommended by the CDC. The bill changes the reference to "pneumococcal vaccination" to allow nursing homes options. The bill also revises the law to clarify that the assessment upon admission is for vaccination or revaccination.

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Nursing homes, which are required to vaccinate eligible residents for pneumococcal disease, may benefit as a result of having additional vaccine options from which to choose.

C. Government Sector Impact:

The DOH will incur indeterminate expenses related to the administration of the study group and reimbursement of members' travel expenses as authorized by the bill. These amounts are not currently known and will vary depending on the size of the group, the location of the appointed representatives, and the frequency of in-person meetings.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.141 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on April 1, 2014:
The committee substitute:

- Deletes all provisions of the bill and substitutes new provisions.
- Requires the DOH to convene a study group of affected stakeholders to assess the effectiveness of the state's current system of surveillance and response to antibiotic-resistant bacteria.
- Requires the study group to submit a report of its findings and recommendations for necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.
- Updates a reference in statute to the pneumococcal vaccine that is provided to nursing home residents upon admission.

B. Amendments:

None.