

Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 641—Chapter 2
“Hepatitis Programs”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 135.19
State or federal law(s) implemented by the rulemaking: No answer provided

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 28, 2023
10 a.m.

Via video/conference call:
meet.google.com/nkg-jzin-yvp

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis. Written or oral comments in response to this Regulatory Analysis must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This chapter defines parameters of a viral hepatitis program. This program is designed to identify people most at risk of exposure to viral hepatitis and to distribute information regarding dangers presented by the disease and to make available hepatitis A and hepatitis B vaccinations and hepatitis C testing.

Rule language defines a list of individuals by category who are at an increased risk for viral hepatitis exposure and details the nature of educational information to be provided to such individuals, as well as the form and manner of information distribution. A vaccination and testing program is established offering testing through local health departments, clinics, and community-based organizations to individuals most impacted by the viruses. Agencies offering testing and vaccination services are also to provide education materials, pretest and posttest counseling, and referral services.

Analysis of Impact

1. Persons affected by the proposed rulemaking:
 - Classes of persons that will bear the costs of the proposed rulemaking:
Not applicable.
 - Classes of persons that will benefit from the proposed rulemaking:
Individuals at increased risk for exposure to viral hepatitis will benefit. Communities in which individuals at increased risk of exposure to viral hepatitis live will also benefit.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:
 - Quantitative description of impact:
Estimated figures below are projections based on past program performance as included in the Red Tape Rule Report for this chapter.

Identified Impacts*

	SFY2024	SFY2025	SFY2026	SFY2027	SFY2028	5-Year Total
Costs						
HHS Implementation	(\$129,000)	(\$130,000)	(\$128,000)	(\$128,000)	(\$127,000)	(\$642,000)
Benefits						
Improved Public Health & Safety	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative	Qualitative
Net Value	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate	Indeterminate

*All monetary figures have been rounded to the nearest thousandth.

- Qualitative description of impact:

Providing access to vaccination and testing for individuals most at risk of exposure to viral hepatitis prevents further spreading of the virus, thus protecting public health and safety. Testing individuals increases the number of people at increased risk of exposure who are aware of their hepatitis C virus (HCV) status. This allows for individuals living with HCV to be linked to treatment earlier preventing costly medical conditions including cirrhosis and hepatocellular carcinoma. In 2022, contracted agencies conducted 1,026 HCV tests and identified 47 people living with HCV. This represented 6.9 percent of all new diagnoses in Iowa in 2022 (compared to 4.3 percent in 2021 and 4.1 percent over the five-year period).

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

HHS incurs costs for personnel, test kits, vaccines, and processing of laboratory tests at the State Hygienic Laboratory. Testing and vaccination is provided through contracted services. These costs are reflected in the table above as “HHS Implementation.”

- Anticipated effect on state revenues:

No impact on state revenues has been identified.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The cost benefit analysis above shows a net value of improved public health and safety. Eliminating the viral hepatitis program, or components thereof, would result in a decrease in available education, testing, vaccination, and treatment of the virus. This may result in increased community spread and a negative impact on public health and safety.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

Tests and vaccines are offered to Iowans at no cost on a voluntary basis. Local public health and community-based organizations are reimbursed for their time and effort. This chapter defines those at increased risk of exposure to viral hepatitis as outlined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. HHS has established parameters for education, testing, and vaccination at the level the Department of Public Health feels necessary to protect public health and safety. A less costly method has not been identified to achieve the purpose of this rulemaking.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

HHS implements the viral hepatitis program in accordance with requirements of the Iowa Code. The Department has flexibility in setting parameters for educational information to be provided to individuals

at risk of exposure, as well as the form and manner of information distribution. The Department also has some flexibility in establishing testing and vaccination parameters for local health departments, clinics, and community-based organizations conducting testing under the program.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

HHS believes the parameters established in this chapter for education, testing, and vaccination are at a level necessary to protect public health and safety.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

Not applicable.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 2 and adopt the following **new** chapter in lieu thereof:

CHAPTER 2 HEPATITIS PROGRAMS

VIRAL HEPATITIS PROGRAM—VACCINATIONS AND TESTING

641—2.1(135) Definitions. For the purpose of these rules, the following definitions shall apply:

“*Contracted agencies*” means local health departments, clinics, and community-based organizations that are funded by the department to provide HCV testing and vaccination services.

“*HCV*” means the hepatitis C virus as defined by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

“*HIV*” means the same as defined in Iowa Code section 141A.1.

“*Viral hepatitis*” means inflammation of the liver caused by one of several viruses: hepatitis A, B, C, D, and E.

641—2.2(135) Exposure risks for hepatitis C virus. The following individuals are at increased risk of exposure to HCV as described by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services:

- People living with HIV;
- People who have ever injected drugs;
- People with selected medical conditions, including those who ever received maintenance hemodialysis;
- Recipients of clotting factors made before 1987;

- e.* Recipients of blood transfusions, blood products, and organ transplants that occurred before 1992;
- f.* Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood; and
- g.* Infants born to mothers living with HCV.

641—2.3(135) Information for public distribution. The department will make available educational materials to the public on hepatitis C infection, transmission, and where to seek testing services as defined on the department's website.

641—2.4(135) Hepatitis vaccination and testing program.

2.4(1) When sufficient state and federal funds are available, the department will maintain a vaccination and testing program. The program shall offer HCV testing and hepatitis A and B vaccinations through local health departments, clinics, and community-based organizations to individuals at an increased risk of exposure to viral hepatitis as described in the Viral Hepatitis Prevention and Testing Services Manual dated December 2023 and available on the department's website. Contracted agencies offering testing and vaccination services shall be required to provide integrated HIV, viral hepatitis, and sexually transmitted infection education; pretest and posttest counseling; and referral services.

2.4(2) Contracted agencies shall provide individuals presenting for testing and/or vaccination services with education explaining viral hepatitis and how to reduce the risk of acquiring it.

2.4(3) Contracted agencies shall provide individuals testing positive for viral hepatitis with information about the diagnosis and treatment options and with a referral list of health care providers to aid in seeking treatment, additional follow-up testing, and other hepatitis-related services.

These rules are intended to implement Iowa Code section 135.19.