Virginia Regulatory Town Hall

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Exempt Action Final Regulation Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC76-20-10 et seq.
Regulation title	Regulations Governing the Prescription Monitoring Program
Action title	Information necessary to qualify for federal funding
Final agency action date	2/9/11
Document preparation date	2/9/11

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments to section 40 on standards for the manner and format of reports to the Prescription Monitoring Program are adopted pursuant to § 54.1-2521, which grants authority to the Director to require "any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds."

The National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) created a formula grant program under the authority of the Secretary for Health and Human Services. In order to qualify for federal funding available since 2010, Virginia's Prescription Monitoring Program is required to include certain information. States receiving NASPER grants must adopt the 4.1 or higher version of the American Society of Automation in Pharmacy (ASAP) reporting standard to ensure that gross formatting errors are minimized. In 42 USC 280g-3, the Secretary is

required to "specify a uniform electronic format for the reporting, sharing and disclosure of information under this section." To that end, The Secretary has identified the ASAP 4.1 reporting standard; subsection A of section 40 is amended to identify that standard as the format pharmacies must use for reporting data.

Data elements of the required report, set out in 42 USC 280g-3 are already listed in §54.1-2521 of the Code of Virginia or are added in new subsection E of section 40, several of which are already included on the current reporting format.

The standards for federal funding in 42 USC 280g-3 further require that the dispenser report to the state after each dispensing of a covered controlled substance not later than one week after the date of dispensing. The timetable for reporting will simply require a pharmacy to program reporting weekly instead of semi-monthly.

Section 2.2-4006 A 4 specifies that regulations necessary to meet the requirements of federal law or regulation are exempt for the operation of the Administrative Process Act. The changes adopted by the Director pursuant to her authority in § 54.1-2521 are necessary to meet the requirements of NASPER.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On February 9, 2011, the Director of the Department of Health Professions amended section 40 of 18VAC76-20-10 et seq., Regulations Governing the Prescription Monitoring Program

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

There is no impact of this action on the institution of the family and family stability.