Agency Name: Department of Health and Environmental Control

Statutory Authority: 44-56-10 et seq.

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Subject: Hypodermic Devices; and Drugs and Devices

History: 4468

By Date Action Description Jt. Res. No. Expiration Date

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- 01/13/2015 Received by Lt. Gov & Speaker 05/13/2015

H 01/13/2015 Referred to Committee

S 01/13/2015 Referred to Committee

H 03/03/2015 Resolution Introduced to Approve 3749

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 provided for in the Regulation

Document No. 4468

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-56-10 et seq.

61-11. Hypodermic Devices

61-18. Drugs and Devices

**Synopsis:**

In the interest of good government and efficiency, the Department is repealing R.61-11, *Hypodermic Devices*, and R.61-18, *Drugs and Devices*. These regulations have become obsolete and are no longer needed or enforceable. See Statement of Need and Reasonableness and Rationale herein.

A Notice of Drafting for the proposed repeals was published in the *State Register* on May 23, 2014.

**Instructions:** Repeal R.61-11 and R. 61-18 in the S.C. Code of Regulations.

**Text:**

61‑11. [Repealed]

61‑18. [Repealed]

**Fiscal Impact Statement:**

The repeal of R.61-11 and R.61-18 will have no substantial fiscal or economic impact on the State and its political subdivisions.

**Statement of Need and Reasonableness:**

This Statement of Need and Reasonableness complies with Section 1-23-115(c)(1)-(3) and (9)-(11), S.C. Code of Laws, 1976, as amended.

DESCRIPTION OF REGULATION: R.61-11, *Hypodermic Devices,* and R.61-18, *Drugs and Devices*.

Purpose: The purpose is to repeal Regulations 61-11 and 61-18 because they have become obsolete and are no longer needed. See Determination of Need and Reasonableness below.

Legal Authority: Code Sections 44-1-140 and 39-23-10 et seq., S.C. Code of Laws, 1976, as amended; 2002 Act No. 365, Section 5.

Plan for Implementation: Upon final approval of the S.C. General Assembly and publication in the State Registeras final, these regulations will be repealed.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-11 was promulgated pursuant to Article 7, Title 44, Chapter 53, “Hypodermic Needles and Syringes.” The Article was repealed by 2002 Act No. 365, Section 5, effective September 26, 2002, with the exception of Section 44-53-930 addressing retail sales by pharmacists, Section 44-53-950 excepting veterinarians and licensed durable medical equipment providers, and Section 44-53-960 outlining penalties. R.61-18 was promulgated pursuant to Title 39, Chapter 23, “Adulterated, Misbranded or New Drugs and Devices.” Regulation 61-18 is not necessary because the items it regulates are currently addressed in state statute and federal law. Therefore, in the interest of good government and efficiency, the Department proposes to repeal these regulations because they are no longer needed.

DETERMINATION OF COSTS AND BENEFITS:

The repeal of R.61-11 and R.61-18 will have no substantial fiscal or economic impact on the State and its political subdivisions or the regulated community.

UNCERTAINTIES OF ESTIMATES:

No know uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There will be no environmental or public health effect.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will not be a detrimental effect on the environment or public health. However, repeal of these regulations is necessary to clarify they are no longer valid or enforceable.

**Statement of Rationale:**

Upon Review of Department regulations, state and federal laws, and the status of R.61-11 pursuant to 2002 Act No. 365, Section 5, it was determined that Regulations 61-11 and 61-18 should be repealed because they are obsolete and no longer necessary.