



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • <http://www.dshs.state.tx.us>

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IMPORTANT NOTICE FOR RETAILERS OF PSEUDOEPHEDRINE AND EPHEDRINE CONTAINING OVER-THE-COUNTER DRUGS

This notice is to advise you that the Texas Department of State Health Services (DSHS) has adopted new 25 Texas Administrative Code (TAC), §§230.11-230.16, concerning Limitations on Sales of Products Containing Ephedrine, Pseudoephedrine, and Norpseudoephedrine. The Commissioner of Health and Human Services approved the proposed rules and they were published in the February 24, 2006 issue of the *Texas Register* (31 TexReg 1170). Following a 30-day public comment period, the final rules were adopted with changes to the proposed text and published in the June 16, 2006 issue of the *Texas Register* (31 TexReg 4863). The rules became effective on June 19, 2006. These sections were adopted under the authority of Health and Safety Code, Section 486.003, which provides DSHS with authority to adopt necessary regulations pursuant to the enforcement of this Chapter; and under Health and Safety Code, Section 12.001, which provides the Commissioner of Health and Human Services with authority to adopt rules for the performance of every duty imposed by law upon DSHS. A copy of the new rules may be found on our website at <http://www.dshs.state.tx.us/dmd/dmdrules.shtm>. We strongly encourage you to read and become familiar with the new sections.

These new sections are necessary to comply with Health and Safety Code (HSC), new Chapter 486, relating to the over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine. Under the new chapter, any business establishment (other than a pharmacy licensed by the Board of Pharmacy) that wishes to engage in over-the-counter sales of products containing any quantity of ephedrine, pseudoephedrine, or norpseudoephedrine must have a certificate of authority (COA) from the department. In order to obtain a COA, a business must: file an application with the department; pay the required fee (\$600 for two years); and agree to comply with the restrictions to access and record keeping requirements of these sections. Compliance with these sections will be verified through audits and inspections.

Please visit the following website if you wish to download an initial or renewal application: <http://www.dshs.state.tx.us/fdlicense>. If you have technical questions about completing the application, please call the Food and Drug Licensing Group at (512) 834-6626. If you have questions about the content of the rules, or need additional information, please contact the Drugs and Medical Devices Group at (512) 834-6755.