



Original Research

# U.S. community pharmacies as CLIA-waived facilities: Prevalence, dispersion, and impact on patient access to testing

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## Abstract

**Background:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA) enabled greater access to low-risk tests by allowing their use in facilities with a Certificate of Waiver in the U.S. Community pharmacies are among the most accessible health professionals, and they are increasingly offering CLIA-waived tests. This manuscript aims to determine: 1) the current number of pharmacies in the United States with CLIA-waivers; 2) the uptake of CLIA-waivers by different pharmacy store types; and 3) the state-by-state differences in the percentage of pharmacies with a CLIA-waiver.

**Methods:** Data were collected from the U.S. Centers for Disease Control and Prevention CLIA Laboratory Search website on May 3rd, 2015. The website allows for exportation of demographic data on all CLIA-waived facilities by state.

**Results:** Pharmacies are currently the fourth highest-ranking facility of CLIA-waived laboratories with 10,838 locations. Supermarkets had the highest percentage of pharmacies with a CLIA-waiver (43.16%). States demonstrated considerable variability in the percentage of pharmacies with a CLIA-waiver, with a median percentage of 19.56% (0%–60.00% range).

**Conclusions:** Community pharmacies are currently a leading facility for CLIA-waived laboratories. Substantial state-level variation is observed in the percentage of pharmacies with CLIA-waivers, and these

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differences may be driven by restrictions in state law or regulations.

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## Introduction

The U.S. Clinical Laboratory Improvement Amendments of 1988 (CLIA) enabled greater access to simple, low-risk tests by allowing their use in facilities with a Certificate of Waiver.<sup>1</sup> The number of analytes for which CLIA-waived test systems are available has grown from nine in 1993, to 123 in 2015 as a result of rapid innovation in technology.<sup>1,2</sup> CLIA-waived tests are now available to detect pregnancy, diagnose influenza, screen for substance abuse, or monitor patients with diabetes, among other uses. Further growth in the number of CLIA-waived tests available is expected in the years ahead.

Convenient access to CLIA-waived tests can aid in diagnosis and speed time to treatment. Increased access to CLIA-waived tests thus has the potential to enhance patient care. The number of access points for CLIA-waived tests in facilities with a CLIA Certificate of Waiver has seen rapid growth, from 67,294 in 1993, to 170,404 in November 2014.<sup>3</sup> Common CLIA-waived facilities include physician offices, skilled nursing facilities, home health agencies, community clinics, and ambulances.<sup>4</sup>

Increasingly, CLIA-waived tests are also being offered at community pharmacies. One of the potential benefits of pharmacy-based testing is accessibility. Community pharmacists are among the most accessible health professionals in the United States, with 95% of all Americans living within 5 miles of a pharmacy.<sup>5,6</sup> Community pharmacies are increasingly offering an expanded suite of clinical services; for example, the number of pharmacy-based immunizations has grown rapidly, and 1 in 5 flu shots is now given in pharmacies partly as a result of their reach and accessibility.<sup>7</sup> Similar growth in access may be possible for CLIA-waived testing. Previous literature has reported on pharmacy-based CLIA-waived testing for influenza, Group A *Streptococcus*, Human Immunodeficiency Virus, Hepatitis C, hemoglobin A1c, cholesterol, and *Helicobacter pylori*, among others.<sup>8–18</sup> In the 2014 National Pharmacist Workforce survey, 29% of respondents indicated that

they conduct “health screening,” 14% reported that they conduct point-of-care testing, and 33% reported that they order laboratory tests.<sup>19</sup> While studies have documented individual CLIA-waived tests that have been leveraged in community pharmacies, a national benchmark report of the prevalence and dispersion of community pharmacies as CLIA-waived facilities has not been reported beyond surveys. This study thus aimed to determine: 1) the current number of pharmacies in the United States with CLIA Certificates of Waiver; 2) the differences in uptake of CLIA-waivers by different pharmacy store types; and 3) the state-by-state differences in the percentage of pharmacies with CLIA Certificates of Waiver.

## Methods

For the purposes of this study, we counted all facilities that held either a CLIA Certificate of Waiver or higher credential (e.g., Certificate of Accreditation, Certificate of Compliance) as a CLIA-waived facility, as those facilities holding these higher credentials may also perform CLIA-waived tests. To determine the number of CLIA-waived facilities by facility type nationally, and the number of pharmacies with a CLIA-waiver in each state, data were collected from the Centers for Disease Control and Prevention (CDC) CLIA Laboratory Search website on May 3rd, 2015.<sup>20</sup> The CDC website allows for a search of CLIA-waived laboratories and includes city, state, zip code, laboratory type (i.e., hospital, physician’s office, pharmacy, etc.), and certificate type (i.e., waiver, accredited, etc.). The authors of the current study conducted searches for all laboratory types and all certificate types for each of the 50 states and the District of Columbia, individually. The results from each state search were exported from the CDC webpage into a Microsoft Excel<sup>®</sup> spreadsheet for further analysis.

Applicants for a CLIA-waiver are required to report their “type of laboratory” that is most descriptive of their facility type. Twenty-nine choices are given for type of facility, one of which

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