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Impact of COVID-19 on prevalence of community pharmacies as CLIA-Waived facilities

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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. Recently, the 2019 novel coronavirus (COVID-19) pandemic has shined a spotlight on CLIA-waived diagnostic testing. To meet this increased patient demand for diagnostic testing, the U.S. Department of Health and Human Services (HHS) authorized licensed pharmacists to order and administer FDA authorized COVID-19 tests.

Objective: This study aims to update the previous national benching report and examine both the number of pharmacies in the United States with CLIA Certificates of Waiver before and after the SARS-CoV-2 pandemic and the state-by-state differences in the percentage of pharmacies with CLIA Certificates of Waiver.

Methods: Data were collected from the U.S. Centers for Disease Control and Prevention CLIA Laboratory Search website May 3rd, 2015, August 4th, 2019 and November 26th, 2020. The website allows for exportation of demographic data on all CLIA-waived facilities by state.

Results: Pharmacies exhibited the largest growth both in number (4865 new locations) and by percent (45%) of CLIA-waived facilities between 2015 and 2020. The total number of pharmacies with a CLIA-waiver grew from 10,626 (17.94%) locations in 2015 to 12,157 (21.43%) locations in 2019, to 15,671 (27.63%) locations in 2020. States demonstrated considerable variability in the percentage of pharmacies with a CLIA-waiver, with a range of 2.92%–56.52%.

Conclusions: Pharmacies have become an increasingly important location for patients to access CLIA-waived tests in the United States, now serving as the second largest provider of CLIA-waived tests by the total number of locations. Most of this growth occurred between 2019 and 2020 due to the COVID-19 pandemic, and concentrated efforts will be necessary to sustain this momentum.

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.¹ Convenient access to CLIA-waived tests can aid in diagnosis, speed time to treatment, and improve clinical outcomes for patients. 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 266,516 in March 2020.²

Common CLIA-waived facilities include physician offices, skilled nursing facilities, home health agencies, community clinics, and ambulances.³

Recently, the 2019 novel coronavirus (COVID-19) pandemic has shined a spotlight on CLIA-waived diagnostic testing. The lack of a vaccine or effective treatment in the early days of the pandemic left diagnostic testing as one of the only tools to control the spread of the virus. To meet this increased patient demand for diagnostic testing, the U.S. Department of Health and Human Services (HHS) authorized

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licensed pharmacists to order and administer FDA authorized SARS-CoV-2 tests.³ In their guidance, HHS noted the close relationships pharmacists have with patients and health care providers as well as the close proximity of pharmacies to most Americans.⁴ States have also rapidly expanded pharmacy-based CLIA-waived testing through both legislative and executive action to increase the capacity of providers and availability of diagnostic testing for COVID-19.^{5,6}

While federal and state action during the COVID-19 pandemic was notable, there has been recent confusion over the authority of pharmacists to perform CLIA-waived tests, as pharmacy-based testing preceded this action.⁷ A national benchmark report of the prevalence and dispersion of community pharmacies as CLIA-waived facilities was completed in 2015.⁷ The report found that pharmacies were the 4th leading provider of CLIA-waived tests by location, equating to 10,838 pharmacies, or 17.94% of all pharmacies nationally at that time.^{8,9} There was a large variability in the percentage of pharmacies with CLIA-waivers by state – ranging from 0% to 60% of pharmacies – that can largely be attributed to differences in state laws and regulations allowing pharmacists authority to perform CLIA-waived tests. A follow-up study conducted in March 2016 found that the number of CLIA-waived pharmacies had fallen by 1,728, primarily due to a large chain pharmacy's corporate decision to not renew CLIA-waivers at many of its locations at the time.¹⁰

This study aims to update the previous national benching report and examine both the number of pharmacies in the United States with CLIA Certificates of Waiver before and after the SARS-CoV-2 pandemic and the state-by-state differences in the percentage of pharmacies with CLIA Certificates of Waiver. This new data will be compared to the original 2015 benchmarking report.

Methods

For the purposes of this study, a methodology identical to the prior national benchmarking report was adopted. 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 were counted, 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, August 4th, 2019 and November 26th, 2020.¹¹ 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® 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 is "pharmacy." The investigators leveraged this self-reported facility type to identify the facilities with the largest number of CLIA-waivers and the number of CLIA-waived laboratories in each state that are in pharmacies. A calculation of the percentage of pharmacies in each state that have a CLIA-waiver using data versus the total number of pharmacies in each state available in the National Association of Chain Drug Stores (NACDS) Fact Book published in 2019 was performed.¹² The investigators treated all self-reported CLIA-waived pharmacies as community pharmacies for the purposes of calculating this percentage.

Results

Table 1 shows the top 10 facilities with a CLIA-waiver or higher in

Table 1
Top laboratory settings by facility count.

Type of Facility	Number of facilities in U.S. with CLIA-waiver or higher credential as of May 2015	Number of facilities in U.S. with CLIA-waiver or higher credential as of November 2020	Percent Change
Physician office	122,634	125,807	3%
Skilled nursing facility/ Nursing facility	14,948	15,573	4%
Home health agency	14,467	13,747	−5%
Pharmacy	10,838	15,703	45%
Hospital	9060	9351	3%
Community clinic	7154	7705	8%
End stage renal disease facility	5990	7425	24%
Ambulatory surgery center	5775	6800	18%
Independent	5424	7154	32%
Ambulance	4093	5234	28%

2015 and their respective numbers in 2020. Pharmacies exhibited the largest growth both in number (4865 new locations) and by percent (45%). As a result, pharmacies became the 2nd ranking location of CLIA-waived facilities, behind physician offices.

Table 2 reports the number and percentage of community pharmacies with CLIA-waivers by state in 2015, 2019, and 2020. Of note, the total number of pharmacies with a CLIA-waiver grew from 10,626 (17.94%) locations in 2015 to 12,157 (21.43%) locations in 2019, to 15,671 (27.63%) locations in 2020. This represents a net increase of 5045 locations from 2015 to 2020. Most of this growth occurred between 2019 and 2020, with 3514 added locations or 70% of the total growth over the study time period.

The percentage of pharmacies holding CLIA-waivers continues to vary substantially by state, with a range of 2.92%–56.52% in 2020. By comparison, the range was 0%–60% of pharmacies per state in 2015. The states with the highest percentage of pharmacies in the state with a CLIA waiver in 2020 were: 1) Washington (56.52%); 2) Alaska (52.69%); and 3) Colorado (51.76%) The states with the lowest percentage of pharmacies with a CLIA-waiver were: 1) Pennsylvania (2.92%); 2) New Jersey (4.10%); and 3) New York (5.54%).

Discussion

Pharmacies have become an increasingly important location for patients to access CLIA-waived tests in the United States. This study demonstrated pharmacies are now the second largest provider of CLIA-waived tests by the total number of locations, which has grown 45% since 2015. By comparison, the total number of community pharmacies nationwide declined by 4% during the same time period.

The growth in the number of pharmacies as CLIA-waived facilities seems to be catalyzed primarily by the growing demand for CLIA-waived tests for SARS-CoV-2. Nearly 70% of the growth in the number of pharmacy locations from 2015 to 2020 occurred over the past year. This is undoubtedly a result of the state and federal action to clarify the legal authority of pharmacists to provide CLIA-waived tests along with concentrated public health efforts to utilize pharmacies as convenient, accessible points of care. The growth is also likely due in part to efforts to strengthen pharmacy-based testing in the education curriculum in recent years.¹³

While nationally there was growth in the number of pharmacies with CLIA waivers, there were four states that saw minor declines over the study period. This is likely attributable to the contraction in the total number of pharmacies and could also be related to a well-publicized incident of purported testing inaccuracy that was temporally

Table 2
State-by-state analysis of community pharmacies as CLIA-waived facilities.

State	Total number of community pharmacies with CLIA-Waivers in 2015	Overall percentage of community pharmacies with CLIA-Waivers in 2015	Total number of community pharmacies with CLIA-Waivers in 2019	Overall percentage of community pharmacies with CLIA-Waivers in 2019	Total number of community pharmacies with CLIA-Waivers in 2020	Overall percentage of community pharmacies with CLIA-Waivers in 2020	Percentage changes in community pharmacies with CLIA-Waivers from 2019 to 2020
Alabama	133	10.48%	362	28.75%	495	39.32%	36.74%
Alaska	48	60.00%	44	47.31%	49	52.69%	11.36%
Arizona	363	36.52%	352	34.38%	328	32.03%	-6.82%
Arkansas	88	12.94%	265	35.05%	295	39.02%	11.32%
California	779	13.84%	510	8.72%	542	9.27%	6.27%
Colorado	213	28.44%	376	48.89%	398	51.76%	5.85%
Connecticut	23	3.59%	64	9.82%	76	11.66%	18.75%
Delaware	52	27.51%	35	18.04%	47	24.23%	34.29%
District of Columbia	15	11.90%	14	9.66%	11	7.59%	-21.43%
Florida	1020	24.05%	1002	22.85%	1431	32.63%	42.81%
Georgia	288	14.10%	449	21.57%	716	34.39%	59.47%
Hawaii	12	6.19%	12	6.25%	22	11.46%	83.33%
Idaho	102	37.50%	144	45.43%	155	48.90%	7.64%
Illinois	668	31.73%	535	25.66%	601	28.82%	12.34%
Indiana	319	28.92%	304	28.36%	326	30.41%	7.24%
Iowa	231	34.79%	271	41.76%	323	49.77%	19.19%
Kansas	140	21.71%	161	27.76%	221	38.10%	37.27%
Kentucky	245	24.14%	332	31.62%	419	39.90%	26.20%
Louisiana	153	14.74%	268	25.02%	345	32.21%	28.73%
Maine	3	1.08%	27	9.64%	89	31.79%	229.63%
Maryland	165	14.96%	208	17.52%	264	22.24%	26.92%
Massachusetts	3	0.27%	2	0.19%	68	6.37%	3300.00%
Michigan	440	19.56%	383	16.42%	681	29.19%	77.81%
Minnesota	243	25.80%	276	28.51%	350	36.16%	26.81%
Mississippi	92	9.47%	194	26.80%	219	30.25%	12.89%
Missouri	375	32.00%	365	28.38%	415	32.27%	13.70%
Montana	53	25.12%	65	29.95%	67	30.88%	3.08%
Nebraska	93	23.08%	107	24.88%	138	32.09%	28.97%
Nevada	-	0.00%	43	9.82%	49	11.19%	13.95%
New Hampshire	26	10.36%	40	15.63%	51	19.92%	27.50%
New Jersey	191	10.24%	52	2.63%	81	4.10%	55.77%
New Mexico	74	26.81%	119	41.32%	130	45.14%	9.24%
New York	17	0.40%	41	0.91%	250	5.54%	509.76%
North Carolina	293	15.17%	428	22.10%	588	30.36%	37.38%
North Dakota	41	37.61%	52	40.31%	56	43.41%	7.69%
Ohio	421	20.23%	519	24.71%	660	31.43%	27.17%
Oklahoma	89	11.14%	198	24.47%	251	31.03%	26.77%
Oregon	129	21.72%	114	19.35%	94	15.96%	-17.54%
Pennsylvania	45	1.66%	61	2.22%	80	2.92%	31.15%
Rhode Island	1	0.53%	13	6.95%	18	9.63%	38.46%
South Carolina	180	17.95%	153	15.03%	330	32.42%	115.69%
South Dakota	27	15.88%	43	24.57%	47	26.86%	9.30%
Tennessee	301	20.60%	409	28.44%	485	33.73%	18.58%
Texas	1184	27.19%	1377	28.38%	1638	33.76%	18.95%
Utah	156	33.69%	222	44.40%	245	49.00%	10.36%
Vermont	14	11.02%	14	12.61%	12	10.81%	-14.29%
Virginia	332	22.48%	404	27.43%	513	34.83%	26.98%
Washington	522	48.60%	427	38.13%	633	56.52%	48.24%
West Virginia	108	20.57%	139	26.83%	153	29.54%	10.07%
Wisconsin	98	10.33%	123	12.68%	163	16.80%	32.52%
Wyoming	18	16.67%	39	32.77%	53	44.54%	35.90%
Totals	10,626	17.94%	12,157	21.43%	15,671	27.63%	28.91%

associated with one pharmacy chain not renewing some of its CLIA-waivers.^{10,14,15}

The growth in pharmacy-based CLIA-waived testing during the COVID-19 pandemic is similar to the growth in pharmacy-based vaccinations during the 2009 H1N1 influenza pandemic. Pharmacists had started providing vaccines in community pharmacies over a decade prior to the pandemic, but the concentrated efforts to mass immunize the population permanently changed where vaccines were sought, with nearly 1 in 3 vaccines now provided in community pharmacies.^{16,17}

The question remains whether this increase is sustainable or if the number of CLIA-waived pharmacies will return to pre-pandemic levels. While the pharmacy-based vaccination gains have continued long after the 2009 H1N1 pandemic, this is likely due to the fact consumers

routinely sought vaccines from other venues, including the annual influenza vaccine, prior to the pandemic. Whether or not a parallel can be drawn with SARS-CoV-2 testing will be a subject of research in the years ahead. It is unknown how demand for SARS-CoV-2 -testing will be after the introduction of a reportedly effective vaccine, and how much consumers will seek other CLIA-waived tests at pharmacies.¹⁸ Further, while payment for pharmacy-based vaccines is supported under Medicare, the payment environment for pharmacy-based testing is less established.

Part of the answer to the question of sustainability will be determined by the state legal environment for pharmacy-based testing. The HHS guidance for pharmacies is limited to the time duration of the COVID-19 pandemic, and thus state laws will be critical to services

continuing. It is clear there are state-level legal impediments hindering uptake, hence the wide range of pharmacies with CLIA-waivers in any given state (2.92%–56.52%). Nevada provides one example of a state that amended its laws, leading to greater uptake. In 2015, 0% of Nevada pharmacies held a CLIA-waiver; this increased to 49 pharmacies, or 11.19%, in 2020. Nevada passed legislation in 2017 to enable pharmacist testing and provided targeted guidance to pharmacists about COVID-19 testing in 2020.^{19–21}

While some state-level impediments to providing testing have been resolved, as Nevada demonstrates, another barrier to demand moving forward will be the ability of pharmacists to act on the results of tests. Influenza and Group A Streptococcus are among the most common tests provided in community pharmacies.^{22,23} The advantage of such tests is to identify patients with these minor ailments and initiate therapy quickly. If pharmacists do not have the ability to act on the tests, there is arguably less benefit, and therefore likely less demand for these services.

Recent changes in state laws show encouraging signs that the ability of pharmacists to act on the results of tests is growing. Effective July 1st, 2020 pharmacists in Florida will have the ability to perform clinical tests and act upon the results.²⁴ Pharmacists in Florida now have the ability to screen for and treat minor, nonchronic health conditions (influenza, Group A streptococcus, etc.) without a collaborative practice agreement. Similar momentum has been seen in states as different politically, and geographically, as Idaho, Vermont, and Kentucky, allowing pharmacists to prescribe certain medications, including those that may be based on the results of CLIA-waived tests.^{25–27} State pharmacy associations, and importantly, public health stakeholders, have an important role to play in ensuring the gains in CLIA-waived test accessibility during COVID-19 sustain beyond the emergency phase of the pandemic.^{28,29} Efforts should be directed at removing state barriers to both testing and acting on the results of tests.

Conclusion

Pharmacies have become an increasingly important location for patients to access CLIA-waived tests in the United States, now serving as the second largest provider of CLIA-waived tests by the total number of locations. The number of community pharmacies with CLIA-waivers grew from 10,626 (17.94%) locations in 2015 to 15,671 (27.63%) locations in 2020. Most of this growth occurred between 2019 and 2020 due to the COVID-19 pandemic, and concentrated efforts will be necessary to sustain this momentum.

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Nicklas S. Klepser: Data curation, Formal analysis, Writing - original draft. **Donald G. Klepser:** Conceptualization, Methodology, Writing - review & editing, Supervision. **Jennifer L. Adams:** Conceptualization, Writing - review & editing. **Alex J. Adams:** Conceptualization, Methodology, Writing - review & editing. **Michael E. Klepser:** Conceptualization, Methodology, Writing - review & editing.

Declaration of competing interest

N/A.

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