

United States Senate

WASHINGTON, DC 20510

December 7, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write to you today to provide an update on the findings of two inquiries we opened in response to concerns regarding the country's coronavirus disease 2019 (COVID-19) testing capacity.

For nearly ten months, the United States has struggled to contain the novel coronavirus and has had more COVID-19 cases and deaths than any country in the world.¹ As we head into the winter, the nation is experiencing yet another resurgence in cases with troubling new national records dwarfing previous spikes.² Once again, lab companies are sounding the alarm that the demand for COVID-19 tests is likely to overwhelm their capacity,³ which will have troubling implications for our country's ability to fully understand and address the ongoing public health crisis caused by the virus.

Earlier this year, we led 44 of our colleagues calling on Vice President Mike Pence, Head of the White House Coronavirus Task Force, and the Federal Emergency Management Agency to conduct a national inventory of the COVID-19 diagnostic testing supply, publicly release data on testing results, and provide a detailed plan and timeline for addressing future shortages and gaps in the testing supply chain.⁴ To this day, the Trump Administration has failed to create a national testing plan, implement a robust testing infrastructure, and address supply chain problems to ensure that our testing system is not overwhelmed and all Americans have swift access to a COVID-19 test.

To learn about the scope of the failed Trump Administration response, and to understand how to fix it we opened two inquiries. First, on August 26, 2020, we wrote to five of the largest COVID-19 testing laboratories regarding each company's capacity to process COVID-19 diagnostic tests

¹ Johns Hopkins University, "New Cases of COVID-19 in World Countries," <https://coronavirus.jhu.edu/data/new-cases>.

² New York Times, "U.S. Records 100,000 Cases in a Day for the First Time," <https://www.nytimes.com/live/2020/11/04/world/covid-19-coronavirus-updates>.

³ Politico, "Labs sound alarm on coronavirus testing capacity, supplies," David Lim, November 12, 2020, <https://www.politico.com/news/2020/11/12/coronavirus-testing-capacity-labs-concerned-436399>.

⁴ "Warren, Smith, Murray Lead 43 Colleagues in Push for More Information, Transparency on Coronavirus Testing Across Country," April 10, 2020, <https://www.warren.senate.gov/oversight/letters/warrensmith-murray-lead-43-colleagues-in-push-for-more-information-transparency-on-coronavirus-testing-across-country>.

and deliver prompt results.⁵ In response to reports over the summer of long wait times for COVID-19 diagnostic test results—with some individuals forced to wait up to two weeks for results—we requested information on the number of tests each company was performing, their average turnaround time, and any supply shortages that hampered their ability to deliver test results in a timely fashion.

The companies' responses revealed the following:

- **Lab companies experienced a large spike in COVID-19 diagnostic testing needs during the summer surge.** Over the summer, in response to a surge in the spread of COVID-19, hundreds of thousands of Americans flooded testing sites.⁶ This spike quickly exceeded the original surge the country experienced in March when the pandemic first began and by early July, more than 33 states across the country were again experiencing an upward trend in cases.⁷ This demand for tests appeared to exceed the nation's capacity.⁸ The five companies surveyed processed over three million tests in just one week in July. One company alone experienced a 28% month-over-month increase in the number of tests processed in August and another reported that the number of tests they performed almost doubled in this time period alone.⁹ On average, it took over three days after specimen pick-up for lab companies to process test samples during several weeks in July and August, compared to just over one day before and after the surge.¹⁰ In this same time period, no company reported a turnaround time of less than 48 hours between testing and the notification of results to the patient.¹¹ Lab companies are concerned about spikes in demand for testing and what this will mean for their future operations.
- **Lab companies have developed additional capacity, but continue to struggle with shortages in supplies.** In response to the surge over the summer, labs worked to increase their testing capacity. One of the most significant limiting factors in the processing of COVID-19 diagnostic testing was an extreme shortage in testing supplies and other crucial materials.¹² Since the surge, several of the testing companies have reported working with vendors to procure additional testing materials such as swabs and reagents. One company has purchased additional instruments, hired supplementary staff, and even constructed a new COVID-specific laboratory to bolster their testing capacities. However, continued strains on the nation's supply chain of critical testing materials and

⁵ Press Release, "Senators Warren and Smith Request Information on Capacity of COVID-19 Testing Labs to Process Diagnostic Tests," <https://www.warren.senate.gov/oversight/letters/senators-warren-and-smith-request-information-on-capacity-of-covid-19-testing-labs-to-process-diagnostic-tests>.

⁶ The Atlantic, "A Devastating New Stage of the Pandemic," Robinson Meyer and Alexis Madrigal, June 25, 2020, <https://www.theatlantic.com/science/archive/2020/06/second-coronavirus-surge-here/613522/>

⁷ CNN, "Americans made 'tremendous sacrifices.' The great reopening of the pandemic summer still got derailed," Ray Sanchez, July 9, 2020, <https://www.cnn.com/2020/07/09/us/us-coronavirus-summer-reopening/index.html>.

⁸ Data compiled from responses from testing lab companies to Sens. Warren and Smith, June-August 2020.

⁹ Data compiled from responses from testing lab companies to Sens. Warren and Smith, June-August 2020.

¹⁰ Data compiled from responses from testing lab companies to Sens. Warren and Smith, June-August 2020.

¹¹ Data compiled from responses from testing lab companies to Sens. Warren and Smith, June-August 2020.

¹² New York Times, "'At War With No Ammo': Doctors Say Shortage of Protective Gear Is Dire," Andrew Jacobs, Matt Richtel, Mike Baker, March 19, 2020, <https://www.nytimes.com/2020/03/19/health/coronavirus-masks-shortage.html>.

personal protective equipment have hampered companies' ability to process tests and secure additional supplies. Four of the five surveyed companies reported shortages in supplies that limited their ability to conduct diagnostic tests and additional shortages in supplies such as swabs, tubes, transportation materials, masks, and other personal protective equipment have also negatively impacted lab companies' ability to perform tests. Additionally, staffing shortages have further negatively impacted lab companies' ability to perform tests and deliver their results in a timely manner.

- **Lab companies have experienced confusion about payment and reimbursement for COVID-19 diagnostic testing as a result of Congressional and Administration inaction.** While Congress has passed legislation to require health insurers cover and “not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization” for COVID-19 diagnostic tests, lab companies have reported that “insurers have been restricting coverage for antibody tests and even RT-PCR testing, particularly for asymptomatic individuals.”¹³ Four of the five lab companies reported that they had encountered issues regarding payment for COVID testing and have already “begun to experience significant claim denials by commercial insurers.” There is little clarity regarding which patients insurers are willing to cover (i.e. asymptomatic vs. medically necessary) and hundreds of claims have already been rejected. This variance in coverage has left both the lab companies and patients confused and forced to foot the bill. All five lab companies called on Congress and the Administration to clarify when third-party payers, the government, or other responsible parties should provide reimbursement for various types of COVID-19 testing, including for diagnostic, screening, or surveillance purposes. They also recommended that Congress designate additional federal funding to pay for surveillance and additional testing.

In addition to this initial investigation, on October 7, 2020, in response to reports that families were having difficulty obtaining COVID-19 testing for their young children,¹⁴ we wrote to the retail providers participating in the Department of Health and Human Services (HHS) Community-Based Testing Sites partnership to ask for information about their policies regarding pediatric testing and their plans to expand testing to more age groups.¹⁵ Pediatric testing is essential to preventing young children from spreading COVID-19 to family members, classmates, and caregivers, especially as children return to school and child care settings. Our letters asked for information about how many testing sites currently offer testing for children under age 18, how many tests have been performed for children, the demographics of site locations and tests performed, and plans to expand testing for pediatric patients. The providers' responses, which are attached, revealed the following:

¹³ Centesr for Medicare and Medicaid, “FAQS About Families First Coronavirus Response Act And Coronavirus Aid, Relief, And Economic Security Act Implementation Part 42,” April 11, 2020, <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf>; Data compiled from responses from testing lab companies to Sens. Warren and Smith, June-August 2020.

¹⁴ New York Times, “It’s Not Easy to Get a Coronavirus Test for a Child,” Sarah Kliff and Margot Sanger-Katz, September 8, 2020, <https://www.nytimes.com/2020/09/08/upshot/children-testing-shortfalls-virus.html>.

¹⁵ Letters to CVS Health, Kroger, Rite Aid, Walgreens, Walmart, and National Community Pharmacists Association from Senators Warren and Smith, October 9, 2020, <https://www.warren.senate.gov/newsroom/press-releases/warren-smith-question-top-retail-testing-providers-companies-on-lack-of-pediatric-testing-at-their-covid-19-testing-sites>.

- **Pediatric testing is becoming more widely available, but most retail providers are not offering testing for young children.** In their responses, several retail providers outlined plans to expand pediatric testing. Walgreens announced on October 15, 2020 – one week after receiving our letter – that their sites would now offer testing to children as young as three years old.¹⁶ CVS Health, which had already expanded testing to children twelve years and older, reported to us that they are planning to expand self-swab testing to children as young as ten years old and that they are exploring having pharmacy personnel administer tests for children under age ten.¹⁷ Rite Aid recently announced that it would be expanding testing to patients as young as 13.¹⁸ At Walmart, there is no restriction on age; the availability of pediatric testing depends on orders by the prescribing health care provider.¹⁹
- **The primary barrier to expanding pediatric testing is the “self-swab” method.** Three providers, including CVS Health (which operates approximately 70% of the country’s retail testing sites), reported that their COVID-19 testing protocol relies on the patient to self-administer a swab test.²⁰ The providers expressed concerns about whether caregivers would be able to successfully conduct this test for young children. In order to expand access to pediatric testing, support from HHS may be needed to administer tests to young children or provide access to different types of tests that are easier to administer to young children.
- **Independent pharmacies have had difficulty participating in HHS’s Community-Based Testing Sites partnership.** The National Community Pharmacists Association reported that fewer than 200 independent pharmacies are participating in the HHS program, while the majority of independent pharmacies have been “effectively shut out” due to lack of access to tests.²¹ Independent pharmacies often serve rural and medically underserved communities that do not have retail pharmacy chains, making their inclusion in the HHS Community Based Testing Sites program especially crucial.²²

Together, our findings reveal significant gaps in COVID-19 testing capacity, exacerbating the ongoing public health threat. Addressing these problems will require aggressive federal government action. We have previously called for dedicated federal funding and a national

¹⁶ Letter from Charles Greener, Walgreens Boots Alliance, to Senators Warren and Smith, October 21, 2020, see attached.

¹⁷ Letter from Melissa Schulman, CVS Health, to Senators Warren and Smith, October 21, 2020, see attached.

¹⁸ Rite Aid, “Rite Aid Updates Covid-19 Testing Program,” November 24, 2020, <https://www.riteaid.com/corporate/news/-/pressreleases/news-room/2020/rite-aid-updates-covid-19-testing-program>.

¹⁹ Letter from Bruce C. Harris, Walmart, to Senators Warren and Smith, October 23, 2020, see attached.

²⁰ *Id.*; Letter from Melissa Schulman, CVS Health, to Senators Warren and Smith, October 21, 2020, see attached; Letter from Heyward Donigan, Rite Aid, to Senators Warren and Smith, October 22, 2020, see attached.

²¹ Letter from Karry K. La Violette, National Community Pharmacists Association, to Senators Warren and Smith, October 20, 2020, see attached.

²² *Id.*

testing plan to ensure that everyone who needs a COVID-19 test can access one quickly and easily.²³ Now, we recommend that the Administration:

1. **Invoke the Defense Production Act** to ensure that testing labs and providers have adequate access to supplies needed to conduct tests and to ensure that supplies are reaching communities that are most in need;
2. **Clarify rules regarding payments for testing** so that patients and providers can more clearly understand when third-party payers, the government, or other responsible parties should provide reimbursement for various types of COVID-19 testing, including for diagnostic, screening, or surveillance purposes;
3. **Provide detailed guidance on appropriate procedures for testing children and education and outreach** to retail providers to enable them to offer pediatric testing services more widely; and
4. **Work with independent pharmacies to address supply chain issues and provide greater access to tests** so that more independent providers are able to participate in the HHS Community-Based Testing Sites program.

We urge you to act quickly to address these gaps. Thank you for your consideration of these urgent matters.

Sincerely,

_____/s/
Elizabeth Warren
United States Senator

_____/s/
Tina Smith
United States Senator

²³ Letter from Senators Elizabeth Warren, Tina Smith, Patty Murray, and colleagues to Vice President Michael Pence, April 10, 2020, <https://www.warren.senate.gov/imo/media/doc/LTO.20-04-09.Diagnostic%20Testing%20Inventory.pdf>; Senator Elizabeth Warren, “Congress Must Move to Rapidly Increase Our Coronavirus Testing Capacity,” March 26, 2020, <https://medium.com/@SenWarren/congress-must-move-to-rapidly-increase-our-coronavirus-testing-capacity-8c5abd71b6f1>.

October 21, 2020

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

The Honorable Tina Smith
United States Senate
Washington, DC 20510

Dear Senators Warren and Smith:

Thank you for contacting CVS Health regarding pediatric testing for coronavirus disease 2019 (COVID-19) at our retail testing sites.

Since the pandemic began, CVS Health has played an important role in helping the country respond. From the early days of the pandemic, we have quickly mobilized our people and resources to offer the first large-scale COVID testing sites in the country and have now completed more than five million COVID tests.

CVS Health is currently providing 70 percent of the testing done in a retail setting. We are currently operating test sites at 4,000 of our drive thru pharmacies. We also operate community test sites serving underserved communities and are providing testing for long-term care facilities.

Additionally, our integrated care model allows us to respond to many of the other health care needs of the communities we serve, including: expanding telemedicine services to make it easier for doctors and patients to connect, and waiving testing and treatment cost-sharing for patients.

With schools opening across the country, we recognized there is a pressing need to make testing for minors more widely available in local communities. To address this, on September 11, 2020, CVS Health announced that children age 12 years and older would be eligible for testing at all of our COVID-19 test sites. To date, we have advised parents or guardians seeking testing for children under the age of 12 to consult with a pediatrician to identify an appropriate testing option. However, we plan to expand our self-swab tests to children as young as 10 at all of our testing sites later this fall, and are reviewing additional options for even younger children using trained personnel at point of care testing locations.

1. What is your company's policy with regard to providing COVID-19 testing for children under the age of 18, excluding newborns?

Children age 12 years and older are eligible for testing at our COVID-19 test sites. A parent or legal guardian must complete the on-line registration for all minor patients, and patients 12 to 15 years of age must be accompanied by a parent or legal guardian when they come to be tested.

2. If your company does not provide COVID-19 testing for all children under the age of 18, excluding newborns, please explain why not.

We do not yet provide COVID-19 testing for all children under the age of 12 because our current testing sites rely on self-swabbing. While we are planning to lower the self-swab age down to 10 years of age, we have concerns about the ability of children under 10 to administer the test accurately themselves. Instead, a parent would have to swab the child, and our clinical experience with this type of testing in MinuteClinic suggests that parents often have difficulties both observing and assisting the swabbing process for their child's test.

We are actively exploring other options, however, including using our Nurse Practitioners (NPs) and Licensed Vocations Nurses (LVNs) from MinuteClinic to administer the tests. These practitioners are well practiced in swabbing young children 18 months and older. This option requires an in-person interaction, however, which is not feasible in a drive thru testing site, but may be possible in other circumstances.

3. How many COVID-19 testing sites does your company currently operate?

We are operating over 4,000 swab and send testing sites, plus an additional 183 point of care testing sites.

a. How many of these sites offer pediatric testing to at least some children under age 18?

All of our sites offer testing for children 12 and above.

b. How many of these sites offer pediatric testing to all children, excluding newborns?

All of our sites offer testing for children 12 and above.

c. How many of these sites offering pediatric testing are located in communities in the highest quartile on the CDC's Social Vulnerability Index?

More than half of CVS Health's testing sites are located in counties that serve moderate to high needs communities, as measured by the CDC's Social Vulnerability Index.

Additionally, CVS Health has partnered with national organizations such as the National Medical Association; local community groups, including free and charitable clinics and community colleges; state governments and the U.S. Department of Health and Human Services to expand community-based testing in multi-racial, underserved areas in more than 10 cities. These community-based test sites are located at the facilities of our partner organizations, enabling us to tap into their networks to expand testing in areas of greatest need and reach people who may not otherwise have easy access to testing. These testing sites are designed to help reduce barriers that may limit access to testing for local residents, including:

- Appointments are made by phone, so lack of internet access is not a barrier.
- Each site can accommodate walk-up testing, so access to a vehicle is not required.
- Signage is offered in English and Spanish.
- Testing is available to patients at no cost.

d. Please provide all of the above requested information at the state level.

State	# Stores	SVI > 0.75	SVI < 0.75	% High SVI
AL	0	0	0	
AK	0	0	0	
AZ	114	24	87	21.60%
AR	0	0	0	
CA	278	158	116	57.70%
CO	0	0	0	
CT	68	0	67	0.00%
DE	0	0	0	
FL	525	94	421	18.30%
GA	235	70	155	31.10%
HI	8	0	8	0.00%
ID	0	0	0	
IL	168	3	156	1.90%
IN	169	36	124	22.50%
IA	0	0	0	
KS	31	4	25	13.80%
KY	38	8	29	21.60%
LA	94	25	49	33.80%
ME	11	0	11	0.00%
MD	75	1	62	1.60%
MA	107	9	96	8.60%
MI	121	32	83	27.80%
MN	46	1	43	2.30%
MS	0	0	0	
MO	82	4	76	5.00%
MT	0	0	0	
NE	17	0	16	0.00%
NV	50	1	48	2.00%
NH	24	0	24	0.00%
NJ	142	16	122	11.60%
NM	13	1	9	10.00%
NY	129	4	123	3.10%
NC	221	47	165	22.20%
ND	0	0	0	
OH	160	3	154	1.90%
OK	58	7	49	12.50%
OR	0	0	0	
PA	204	16	179	8.20%
RI	22	14	8	63.60%
SC	111	28	80	25.90%
SD	0	0	0	
TN	92	12	79	13.20%
TX	572	196	365	34.90%
UT	0	0	0	
VT	0	0	0	
VA	156	10	106	8.60%
WA	0	0	0	
WV	0	0	0	
WI	42	9	33	21.40%
WY	0	0	0	

Total	4183	833	3168	20.80%
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We are also operating our special community sites in Pawtucket, RI, Columbia, SC, Los Angeles, CA, Phoenix, Arizona, Houston, North Houston, and Ft. Worth, TX, Atlanta, GA, Baltimore, MD, and Hartford, CT.

- e. Please provide a list of addresses for sites offering pediatric testing and indicate whether those sites offer comprehensive pediatric testing or have age restrictions.

Please see the attached Excel file entitled "Pediatric Testing Sites."

4. How many COVID-19 tests has your company performed to date?

We have completed approximately five million tests as of 10/19/2020

- a. **Please provide the number of tests performed for patients who were under age 5, under age 12, and under age 18.**

Age Group	# Tests Completed
>12-18	56,350*
18+	4,663,243

*Tests for patients between 12 and 18 only started on Sept 11, while adult Swab & Send testing started on May 15. We did not do any testing for children under the age of 12.

- b. **Are there are any differences in average time between testing and obtaining a result for these different age groups?**

No.

- c. **Please provide a demographic breakdown by the race and ethnicity of these patients, for both adult and pediatric patients.**

The below table provides a demographic breakdown of testing patients. Please note that we have not released this information publically, but are supplying it to you per your request.

Race Breakdown

FirstRace	Grand Total	Over 18	Under 18
*Unspecified	96,753 (2.05%)	95,568 (2.09%)	1,185 (0.80%)
American Indian or Alaska Native	21,515 (0.46%)	20,664 (0.45%)	851 (0.57%)
Asian	311,231 (6.59%)	302,788 (6.62%)	8,443 (5.70%)
Black or African American	620,818 (13.15%)	602,268 (13.17%)	18,550 (12.52%)
Hispanic	886,456 (18.78%)	856,938 (18.75%)	29,518 (19.93%)
Native Hawaiian or Other Pacific Islander	19,073 (0.40%)	18,480 (0.40%)	593 (0.40%)
Other	110,819 (2.35%)	106,332 (2.33%)	4,487 (3.03%)
Patient Refused	70,033 (1.48%)	68,196 (1.49%)	1,837 (1.24%)
Unknown	46,106 (0.98%)	44,823 (0.98%)	1,283 (0.87%)
White or Caucasian	2,536,789 (53.75%)	2,455,411 (53.71%)	81,378 (54.94%)
Grand Total	4,719,593 (100.00%)	4,571,468 (100.00%)	148,125 (100.00%)

Ethnicity Breakdown

Ethnicity	Grand Total	Over 18	Under 18
*Unspecified	97,048 (2.06%)	95,940 (2.10%)	1,108 (0.75%)
Hispanic or Latino	1,032,778 (21.88%)	995,133 (21.77%)	37,645 (25.41%)
Not Hispanic or Latino	3,125,695 (66.23%)	3,028,326 (66.24%)	97,369 (65.73%)
Patient Refused	149,513 (3.17%)	145,913 (3.19%)	3,600 (2.43%)
Unknown	314,559 (6.66%)	306,156 (6.70%)	8,403 (5.67%)
Grand Total	4,719,593 (100.00%)	4,571,468 (100.00%)	148,125 (100.00%)

5. Please describe any plans to expand testing for pediatric patients and the expected timeline for implementation.

We are exploring lowering the self-swab age 10 and older. Additionally, we are investigating other options, including using our Nurse Practitioners (NPs) and Licensed Vocations Nurses (LVNs) from MinuteClinic to administer the tests. These practitioners are well practiced in swabbing young children 18 months and older.

6. Please describe any plans to expand testing access in communities of color and the expected timeline for implementation.

In addition to our retail sites, as noted earlier, CVS Health has partnered with national organizations such as the National Medical Association, local community groups, including free and charitable clinics and Historically Black Colleges and Universities (HBCU), along with state governments and the U.S. Department of Health and Human Services to expand community-based testing in underserved areas in more than 10 cities

7. What are the major barriers to providing expanded access to testing for pediatric patients?

As previously noted, CVS Health is currently testing children age 12 years and older and plans to expand testing to children 10 and older at all of testing sites this fall. To date, we have lacked the pediatric trained personnel at these sites to administer the tests to children younger than 10, but have advised parents or guardians seeking testing for children under the age of 12 to consult with a pediatrician to identify an appropriate testing option. And, as mentioned above, we are reviewing additional options for even younger children using trained personnel at point of care testing locations.

Thank you for your interest in COVID-19 testing at our retail sites, and for giving us the opportunity to share the information and data provided here. As we continue to examine this issue and explore options, we will keep you updated. CVS Health remains committed to helping patients who rely on us to gain access to COVID testing in a timely manner – and we will continue to serve as an advocate for and administer these services during these unprecedented times.

Sincerely,



Melissa Schulman
Senior Vice President, Government and Public Affairs

October 20, 2020

The Honorable Elizabeth Warren
United States Senate
309 Hart Senate Office Building
Washington, DC 20510

The Honorable Tina Smith
United States Senate
720 Hart Senate Office Building
Washington, DC 20510

Dear Senators Warren and Smith:

The National Community Pharmacists Association (NCPA) is writing today in response to your questions on pediatric testing for coronavirus disease 2019 (COVID-19), and we are pleased to share the perspective of America's independent community pharmacies.

NCPA represents America's community pharmacists, including more than 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members represent a \$76 billion healthcare marketplace, employ approximately 200,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers.

As you are aware, the Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Health set forth guidance authorizing licensed pharmacists to order and administer COVID-19 tests. However, the majority of the over 21,000 independent pharmacies have effectively been shut out of current HHS public-private partnerships in place under the Community-Based Testing Sites for COVID-19 program. By our estimate, fewer than 200 independent community pharmacies are currently engaged in COVID-19 testing through these partnerships. Many more would like the opportunity to perform COVID-19 testing but have had problems accessing tests to provide to their patients.

While chain pharmacies are well known by their brand, independent pharmacies are often located in rural and medically underserved areas, are a key connection point to patients, and are vital to achieving the goal of widespread COVID-19 testing and eventual vaccination administration. The 2020 *NCPA Digest* report shows there were approximately 21,683 independent pharmacies in 2019, and 22,773 large national chains. No single pharmacy chain has more stores than all independents combined. A separate NCPA analysis showed that 20.5 percent of zip codes that have a pharmacy do not have a chain drug store, further supporting the case for broad-based utilization of all community-based pharmacy practices.

While most of our members are currently not engaged in testing, the community pharmacies that are performing COVID-19 tests make no distinction on the patients they serve. While we only have anecdotes, it appears independent community pharmacies do not have restrictions on performing tests for pediatric patients that may exist in drive-thru, self-swab retail testing sites. An independent pharmacy in Little Rock, Ark. reported having tested kids as young as two years old so far. A pharmacy in York, S.C. says it has no age restrictions on the testing that it is just now beginning to provide to patients. These two entities are performing actual testing culminating in results for the patient directly, not just sample collection. A pharmacy in Milwaukee that is performing sample collection for testing as part of the Public-Private partnership stated that the partnership does not have an age restriction on sample collection.

Reimbursement for COVID-19 testing also represents a barrier for pharmacies that want to engage in testing. As NCPA understands from the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of the General Counsel's (OGC) guidance, there are currently two pathways for pharmacists to bill Medicare for COVID-19 testing. The first mechanism is where the pharmacy must enroll as an independent clinical lab, and the second mechanism utilizes the incident-to relationship with a physician. NCPA appreciates CMS' flexibilities in expanding pharmacists' ability to provide and administer COVID-19 testing; however, a clear, direct pathway for payment for pharmacists' services under Medicare and Medicaid does not exist.

Medicare and Medicaid coverage of pharmacists' services in providing COVID-19 testing is especially vital at this time due to the prevalence of COVID-19 with influenza season approaching. Therefore, we have asked that CMS create a direct pathway for pharmacists to bill for specimen collection and other related services for patients who come to their pharmacies. Specifically, NCPA strongly urges CMS and/or Congress to temporarily recognize pharmacists as nonphysician practitioners that would allow pharmacists to directly bill during the Public Health Emergency (PHE). Our members are not set up and cannot scale up in time to have incident-to or lab relations in place to address the imminent needs of the PHE.

NCPA released a survey over the summer showing that mobility is one key advantage for community pharmacies. In fact, 70 percent serve patients in locations outside of their brick-and-mortar pharmacies. In the past, they have immunized patients in local businesses, LTC facilities, community centers, schools, prisons, places of worship, voting venues, and other locations. Community pharmacists are willing to go wherever they can to help the most people. Most serve communities with fewer than 50,000 residents, and nearly 40 percent serve communities with fewer than 10,000 residents. Given access to the tests and appropriate reimbursement, community pharmacies could be activated to test and vaccinate the patients they serve, especially in rural and underserved communities.

While we do not have any specific data to provide on the independent pharmacies that are performing COVID-19 testing, we hope these anecdotes are helpful. Independent pharmacies stand ready to assist in this pandemic to perform COVID-19 testing and administer the eventual vaccine, but access to the tests and reimbursement poses a barrier that many pharmacies have not been able to overcome yet, even as more tests become available. Community pharmacies continue to advocate for a more streamlined reimbursement mechanism either through action by federal agencies or legislation from Congress. NCPA thanks you for your leadership in ensuring that all patients have access to COVID-19 testing, and we look forward to working with you to further expand testing in all communities.

Sincerely,



Karry K. La Violette
Senior Vice President of Government Affairs & Director of the Advocacy Center
National Community Pharmacists Association



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GENERAL OFFICE
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Camp Hill, PA 17011

October 22, 2020

The Honorable Elizabeth Warren
U.S. Senate
309 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Tina Smith
U.S. Senate
720 Hart Senate Office Building
Washington, D.C. 20510

Dear Senators Warren and Smith,

I am responding to your letter dated October 8, 2020 on pediatric testing for COVID-19 at our retail testing sites.

As you know, our Rite Aid pharmacists and store associates have been on the front lines from the outset of the pandemic. We partnered with both federal and state governments to stand up COVID-19 drive-thru testing sites to provide testing for Americans at a critical time.

Currently, Rite Aid operates 305 testing sites in 15 states and we have completed ~820,000 tests.

All of our testing sites, utilize self-swab nasal tests overseen by Rite Aid pharmacists. Testing is available at no cost to individuals through our partnership with the Department of Health and Human Services (HHS), regardless if they are experiencing symptoms, that provide a government-issued ID, and pre-register online to schedule a time slot for testing.

At this time, only patients ages 18 and older are being tested at our sites due to our existing testing partnerships. As with all our business relationships, we are constantly evaluating their capabilities and appreciate you highlighting the importance of this issue. We have inquired with our partners about potential solutions for pediatric testing.

Please see below for our detailed responses to your questions. The following paragraphs correspond to those in your letter:

1. What is your company's policy with regard to providing COVID-19 testing for children under the age of 18, excluding newborns?

Rite Aid has partnerships with Verily and PWNHealth to facilitate COVID-19 testing. For testing minors, we are dependent on the policies and processes of our testing partners.

Verily - Their platform is only designed for an adult to consent for themselves, not on behalf of a minor. The results are delivered via email, assuming the email belongs to the individual tested, not a minor/dependent.

PWN – Does have protocols in place to provide orders for minors down to age 13 based on the child's ability to complete the self-swab guided by a provider. For younger children, the provider would be responsible for completing the swab.

The provider swabbing model is not Rite Aid's testing model.

2. If your company does not provide COVID-19 testing for all children under the age of 18, excluding newborns, please explain why not.

Please refer to the above answer for information about the testing limitations of our partners.

3. How many COVID-19 testing sites does your company currently operate?

We currently operate 305 testing sites across 15 states.

a. How many of these sites offer pediatric testing to at least some children under age 18?

None of the sites offer pediatric testing to children under age 18.

b. How many of these sites offer pediatric testing to all children, excluding newborns?

None of the sites offer pediatric testing to all children.

c. How many of these sites offering pediatric testing are located in communities in the highest quartile on the CDC's Social Vulnerability Index?

Not applicable, as none of the sites offer pediatric testing.

d. Please provide all of the above requested information at the state level.

No sites provide pediatric testing.

e. Please provide a list of addresses for sites offering pediatric testing and indicate whether those sites offer comprehensive pediatric testing or have age restrictions.

No sites provide pediatric testing.

4. How many COVID-19 tests has your company performed to date?

As of October 8, we are proud to have performed more than 850,000 COVID-19 diagnostic tests.

a. Please provide the number of tests performed for patients who were under age 5, under age 12, and under age 18.

There is no testing data available for any of the above age groups.

b. Are there any differences in average time between testing and obtaining a result for these different age groups?

There is no difference in reporting results based on age.

c. Please provide a demographic breakdown by the race and ethnicity of these patients, for both adult and pediatric patients.

See the spreadsheet below:

Ethnicity	Ages							Grand Total
	18-19	20-44	45-54	55-64	65-74	75-84	85+	
Hispanic/Latino	7034	80005	16604	10345	3926	967	212	119093
Non-Hispanic/Latino	22812	278631	67006	70458	38842	9510	1818	489077
Not reported	3018	63744	23154	24699	14110	3217	444	132386
Grand Total	32864	422380	106764	105502	56878	13694	2474	740556

5. Please describe any plans to expand testing for pediatric patients and the expected timeline for implementation.

There are currently no plans to expand testing for pediatric patients nor a timeline for implementation of pediatric testing.

6. Please describe any plans to expand testing access in communities of color and the expected timeline for implementation.

We recognize the disproportionate impact COVID-19 continues to have on communities of color. Nationally, 53% of our sites are in communities with 50% or higher minority populations. As Rite Aid expands additional COVID-19 testing sites, we remain committed to ensuring that communities of color have access to testing, vaccinations, and other critical health care services.

7. What are the major barriers to providing expanded access to testing for pediatric patients?

For Rite Aid to provide testing for any individual under 18, we would need a way to collect consent electronically during the screening process with Verily. We would also need a way to deliver the results for the minor through email and/or phone call to the legal guardian. To expand below 13, we would need to have a new testing model that would require a provider to complete the nasal swab for the child. However, Rite Aid is actively working with our partners to be able to offer testing to individuals under the age of 18.

If you have any questions, please do not hesitate to contact Yong Choe, Rite Aid Vice President for Federal Affairs and Public Policy, at Yong.S.Cho@riteaid.com or 703-346-5328.

Thank you for your continued leadership on these important issues.

Sincerely,

A handwritten signature in black ink that reads "Heyward Donigan". The signature is written in a cursive style with a horizontal line at the end.

Heyward Donigan
President and Chief Executive Officer



Walgreens Boots Alliance

October 21, 2020

The Honorable Elizabeth Warren
U.S. Senator
309 Hart Senate Office Building
Washington, DC 20510

The Honorable Tina Smith
U.S. Senator
720 Hart Senate Office Building
Washington, DC 20510

Walgreens would like to thank you for the October 8th request for information regarding pediatric testing for COVID-19 at our testing locations that was addressed to President of Walgreens John Standley. I will answer on his behalf and hope these comments are helpful in understanding Walgreens current COVID-19 testing operations and national presence to best serve our patients and customers.

Walgreens operates approximately 9,200 stores in all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. More than 8 million customers and patients interact with Walgreens each day in communities across America. Through our locations and platforms, customers are using the most convenient, multichannel access to consumer goods and services and trusted, cost-effective pharmacy, health and wellness services and advice. Walgreens scope of pharmacy services includes retail, specialty, medical facility and mail service, as well as online and mobile services. Our services help improve health outcomes and lower costs for payers, including employers, managed care organizations, health systems, pharmacy benefit managers (PBMs) and the public sector.

Since the onset of the pandemic, working closely with government and health officials, manufacturers and distributors, and other industry leaders, Walgreens has helped accelerate the availability of COVID tests, ensured access to essential medicines and products, ramped up our annual flu immunization program, and served as a safe and trusted source of information and resources. A pillar of the pandemic response has been the testing of individuals to identify and isolate infectious persons in order to break the transmission cycle and slow the spread of the disease. Walgreens is proud to leverage our nationwide footprint, community presence and pharmacist expertise to expand access to COVID-19 tests and recently announced we lowered our minimum age for COVID-19 tests to ages 3 and older.

We appreciate your interest in pediatric testing and the opportunity to share what we are doing to help combat the pandemic. Please see responses to your specific questions below.

Responses to the Senator's Request for Information:

- 1. What is your company's policy with regard to providing COVID-19 testing for children under the age of 18, excluding newborns?**

Walgreens began COVID-19 testing for minors that are 3 years of age and older at all sites on October 15, 2020.

- 2. If your company does not provide COVID-19 testing for all children under the age of 18, excluding newborns, please explain why not.**

Walgreens policy is consistent with the Amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) made by Health and Human Services Secretary Azar on August 18, 2020, that authorizes State-licensed pharmacists and pharmacy interns to order and administer vaccines to individuals ages three through 18 years, subject to several requirements.

3. How many COVID-19 testing sites does your company currently operate?

As of October 16, 2020, Walgreens operated 618 sites across 49 states, DC and Puerto Rico.

a. How many of these sites offer pediatric testing to at least some children under age 18?

All Walgreens sites offer testing for patients 3 years of age and older.

b. How many of these sites offer pediatric testing to all children, excluding newborns?

All Walgreens sites offer testing for patients 3 years of age and older.

c. How many of these sites offering pediatric testing are located in communities in the highest quartile on the CDC's Social Vulnerability Index?

Approximately 47.2% are in the 4th quartile (.75-1) of the Social Vulnerability Index (SVI) and more than 80% are in the 3rd quartile (0.50+) and above.

d. Please provide all of the above requested information at the state level.

Please see the attached Excel chart.

e. Please provide a list of addresses for sites offering pediatric testing and indicate whether those sites offer comprehensive pediatric testing or have age restrictions.

Walgreens is adding new sites weekly. You can find the addresses of testing sites on our website at www.walgreens.com/findcare/covid19/testing. All sites listed offer testing for patients 3 years of age and older.

4. How many COVID-19 tests has your company performed to date?

As of October 16, 2020, Walgreens has performed more than 1.4 million COVID-19 tests.

a. Please provide the number of tests performed for patients who were under age 5, under age 12, and under age 18.

Please see the attached Powerpoint.

b. Are there any differences in average time between testing and obtaining a result for these different age groups?

There is no difference in the average time between testing and obtaining a result between different age groups.

- c. **Please provide a demographic breakdown by the race and ethnicity of these patients, for both adult and pediatric patients.**

Please see the attached Powerpoint.

5. **Please describe any plans to expand testing for pediatric patients and the expected timeline for implementation.**

Please see the above responses.

6. **Please describe any plans to expand testing access in communities of color and the expected timeline for implementation.**

A large percentage of Walgreens' existing pharmacy footprint is in communities of color today, so our focus will continue to be to ensure that our testing sites are located in the highest quartiles of the SVI and supporting communities in need.

7. **What are the major barriers to providing expanded access to testing for pediatric patients?**

While we are currently not experiencing any major barriers to providing pediatric testing, we are concerned there may be barriers when a COVID vaccine becomes available for pediatric use specifically in Medicaid programs. Many states require providers to enroll in the Vaccines for Children program in order to provide vaccines under the Medicaid program. However, enrollment in the program is low among most healthcare providers, including pharmacies, due to complex and onerous requirements and historically low reimbursement rates. We believe that if states maintain a requirement to enroll in the VFC program in order to administer the COVID vaccine to children and adolescents, this will become a major barrier to access among this vulnerable, low-income population. We recommend this requirement be waived specifically for the COVID vaccine during the Public Health Emergency.

Conclusion

Thank you again for your inquiry. Walgreens shares your goal of increasing access to health care, particularly for the most vulnerable. We are proud of how pharmacists continue to rise to the challenge in serving the needs of patients in combatting the pandemic and will continue to look for opportunities to better assist the communities we serve. We hope that this information is helpful in best serving your constituents.

Sincerely,



Charles Greener
Senior Vice President and Global Chief Public Affairs Officer
Walgreens Boots Alliance



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Fax: 202.737.6069
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October 23, 2020

The Honorable Elizabeth Warren
309 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Tina Smith
720 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

Senators Warren and Smith:

Thank you for your letter to our CEO Doug McMillon, dated October 7, 2020.

We appreciate your questions regarding our COVID-19 testing efforts. Throughout the COVID-19 pandemic, it has been incredible to see Walmart associates step up to the challenge of serving America. During a very uncertain and stressful time, they have done their jobs with calm, compassion, and excellence. Because of their efforts, Americans have been able to get the items and services they need from clean, orderly stores — or delivered right to their doorsteps.

We remain committed to supporting testing in our communities. As we continue to evolve our testing capabilities, we are expanding testing at our drive-thru pharmacy windows, prioritizing based on community demand and where we can make the most impact. We have continued to learn from our testing sites and become increasingly efficient in how we operate and how we integrate testing into our business. Our goal is to help provide access to testing in our communities and play a part to help combat the pandemic, and we continue to find innovative ways to do just that.

We have about 600 active testing sites across the country in 35 states, which are a mix of Department of Health and Human Services (HHS) community testing sites and partnerships with insurance companies for their members.

Also, we recognize the importance of encouraging customers to get their flu shots this season. To date, we are seeing twice the number of flu shots given by our pharmacies. Demand for flu vaccines is earlier than in previous years and our investment in staffing by pharmacists of two flu clinics per week is helping to provide improved protection to the communities we serve. These clinics are in addition to offering immunizations at the pharmacy open to close, 7 days a week. We ordered twice as many flu doses as last year to ensure we are able to meet the expected demand. So far, we have administered over 2 million flu shots this flu season.

In regard to your questions about access to COVID-19 testing for children, in all of our testing sites, our health care professionals are serving as observers to the patient self-swab of the "PCR" test. In this context, Walmart is not operating as the ordering provider (i.e. the "prescriber" of the test), nor the lab of record. We are not offering "walk-up" testing options without an order from a provider or lab of record.



Our testing sites serve as the place where patients with test orders from a provider and/or a lab of record can go to receive a test. The ordering providers and the labs of record are responsible for determining the age of patients tested. At Walmart, our health professionals will observe a test for any patient with an order from a provider or lab of record -- as long as the patient can either self-administer the self-swab test or have a caregiver present who can assist.

Thank you again for your questions about this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce C. Harris". The signature is fluid and cursive, with a prominent initial "B" and "H".

Bruce C. Harris

Vice President, Federal Government Affairs

Walmart