Business Group on Health

January 14, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

Re: FAQs Part 51 – Regarding Over-the-Counter (OTC) Coverage Requirements under FFCRA Section 6001.

Dear Secretaries Becerra, Yellen and Walsh:

We write to first express our appreciation for the thoughtful approach to the FAQs (Part 51) guidance issued jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) on January 10, 2022. We and our members have now had time to review the guidance and make initial inquiries into the steps that will be necessary to comply. We have also compiled some initial concerns and requests that we believe follow the spirit and the requirements of FFCRA Section 6001 (as amended) and will enable employers to be successful partners with the Administration in the fight to control the pandemic.

Business Group on Health represents a network of more than 440 of today's largest and most progressive employers, including 74 Fortune 100 companies, providing health coverage for 60 million workers, retirees and their families in 200 countries. Business Group members – innovative employer plan sponsors – are leading the way and encouraging others by providing strong health plan offerings, adopting alternative

payment models, managing the total cost of care, promoting health equity, furthering population health, and keeping people well.

I. **Employer plans appreciate the flexibility and continued partnership. Of prime concern is an inability to unilaterally provide the Department's desired "direct coverage" and utilize the Q#2 safe harbor. We urge the Departments to provide relief in the form of delay or the application of a good faith standard for the plan's use of Q#2 safe harbor.**

We read the FAQs to provide necessary flexibility for plans to partner with existing and new vendors in a variety of ways in order to meet the coverage requirements. This broad flexibility is appreciated and recognizes that employer plan sponsors are generally reliant on others, such as insurers/ASO providers, TPAs, PBMs, and other vendors, for at least some part of the coverage or test acquisition that would be required to meet the standards.

Of prime concern for employer plan sponsors, however, given (among other factors) their reliance on other parties, and current supply challenges and shortages of appropriate OTC COVID-19 tests, is the January 15, 2022 effective date for the coverage to begin. With the release of the guidance on January 10, 2022, that provided only 4 business days for employers to digest the requirements and work to establish the coverage. While many large employers anticipated the guidance to be issued this week, even the most resourceful need additional time to work with their vendors or find new vendors. Even basic reimbursement rules and mechanisms may be impossible to implement in this time frame, much less the highly preferred direct coverage under the Q#2 safe harbor.

We understand the urgency of the need for widespread testing and that a delay in the effective date may not be desirable. Practically, though, without a delay of likely 60 to 90 days or the alternative relief and good faith allowances we suggest below, employers may struggle to achieve basic technical compliance by January 15. Additionally, almost certainly, the vast majority of employers will not be confident that their plans are meeting the standards required for the direct coverage safe harbor.

Based on discussions with our members, we expect most employers will want to provide direct coverage envisioned under Q#2. Employers understand the financial and logistical challenges facing their employees and families, and how up-front costs may impede the level of testing needed to control the pandemic. They also value the predictability that would come with a negotiated price for tests from a preferred

provider, and the predictability of the $12 per test limit on tests from non-preferred providers. However, based on the limitations of their role as the plan sponsor and their universal reliance on other parties to breathe life into a direct coverage structure, there is no viable path for any employer to have direct coverage reliably established by January 15, 2022.

This is a demoralizing and harsh reality for many employers and plans who have rowed in unison with the various new initiatives and requirements for nearly two years. The fact is employers cannot act alone to establish direct coverage and have no control over all of the various parties needed to do so. While they may work with an ASO provider, TPA, or PBM generally, they have no guarantee such party will be able or willing to assist with coverage for OTC tests. Further, even if they have a willing and able vendor, they have no assurance such vendor will be able to establish a preferred arrangement in this current market environment. And moreover, retailers and other suppliers are not obligated to make deals with the vendor, the plan directly, or the employer, and may choose not to do so for price, supply, or a myriad of other reasons. Indeed, we are sensitive to suppliers' natural business desire to maximize any gain from the disparity inherent in any market circumstance, like here, where one party is legally compelled to buy (or reimburse) while the other has no such requirement to sell.

We are concerned that a tsunami of employer plans and other coverage issuers attempting to all get preferred arrangements in order to establish direct coverage will lead to market distortions with harmful consequences for everyone seeking tests. This type of urgent consumption or setting of future optional consumption against current and future inventories may lead to inequities for individuals with less resources and smaller companies that are unable to pay top dollar.

We urge the Departments to provide either: (a) a 60 to 90 day delay of enforcement or effective date; or alternatively (b) that employer plans be given the clear ability to adopt and rely upon the Q#2 safe harbor in good faith as of January 15, 2022 (or any time after) and limit any non-preferred reimbursements to $12 per test as long as the employer is working in good faith to establish the no-cost direct coverage network otherwise envisioned. Plans may not immediately have a "no-cost" test supplier available, but as such resource is identified and engaged, good faith effort would include a reasonable timeline to make such resource known to and available to covered individuals. We believe this relief is reasonable and appropriate in light of the challenges, supply shortages, timelines, and other factors discussed above.

II. Many employers will take innovative steps to help ensure direct coverage is provided. Plans request clarification that certain efforts will be considered as part of the coverage and adequacy requirements.

a. Clarify and confirm that direct provision of OTC tests from employers to employees and other covered individuals will be "counted" for purposes of the coverage requirements, including the Q#2 and Q#3 safe harbors.

In prior communications we raised the expectation that some employers may work to directly purchase and provide tests to their workers and/or their covered family members as part of the coverage. We read the FAQ to permit this practice and believe it will be an important part of many employers' ability to implement the Departments' strongly preferred "direct coverage" program. We have, however, received many questions from confused employers who wish to better understand that if the plan identifies and utilizes the employer as a source for the direct provision of OTC tests (either in-person or by shipping) such mechanism will be considered as part of the direct coverage assessment in Q#2. We believe express clarification on this issue would be helpful.

Similarly, any direct provision of tests from the employer to the employee or other covered individuals, we believe should be counted against any applicable maximum available through the Q#3 safe harbor. Again, additional clarification that direct provision of tests from the employer (as the source identified by the plan) will be counted for purposes of Q#3 would be helpful.

b. Clarify and confirm that although not required to be covered, tests provided by employers for employee use for employment (or other non-required) purposes will be counted against the required 8-test maximum provided in Q#3.

Many employers have established testing regimens for their workforces for many months utilizing OTC COVID-19 tests. In general employers are providing these tests at no cost at least once per week to any in-person employee. In many cases employees are required to take the test in order to return to or continue work for the week. And in instances where an employee voluntarily wishes to test or believes they should test because of exposure or other reasons, many employers make such tests available.

It is our understanding there is not a strong consensus or meaningful leaning in the scientific community supporting materially enhanced efficacy and necessity from

testing multiple times per day or within a short one-to-two-day span. It therefore appears that tests provided by employers, even for employment purposes, in a given week or period, each satisfy the need for testing in a particular window. This satisfaction obviates or at least significantly reduces the need for another test in this same period. We note, in our view, whether or not the employer's regimen is required by another legal authority or contractual obligation is immaterial to whether it should be credited for the purposes of required plan coverage. Thus, the plan's obligation to cover tests, including under the Q#2 and Q#3 safe harbors, should count any tests provided by the employer for employment or any other purposes, and we respectfully request the Departments clarify and confirm such allowance in the FAQs.

c. **"Adequate" direct coverage under Q#2 appears to require both in-person and online availability of no-cost OTC tests. The in-person and online delivery channels are different and may not both be readily available through known and/or willing vendors. Plans should be permitted to show "adequate" direct coverage through either or both in-person or online sources in order to move forward with the direct coverage provisions under Q#2.**

As plans work in earnest to explore options for direct coverage, requiring multiple channels (in-person *and* online) exponentially complicates the implementation, tracking, reconciliation, vendor relations, and overall administrative effort. While multi-channel distribution is a desirable consumer experience, plans that are able to provide "adequate" direct coverage through one channel should be permitted to do so and utilize the Q#2 safe harbor. Allowing a plan to focus its effort on one channel promotes efficient implementation, cost-effective economies of scale, and clear communications with covered individuals about how to get the free tests. We respectfully request that plans be permitted to establish and show "adequate" direct coverage through **either or both** in-person **or** online sources.

III. The requirements to utilize the Q#3 safe harbor appear to adopt a "uniform coverage" approach for the 8 test per month (or 30 day period). Plans are concerned this approach does not promote equity or adequately allow fraud and abuse protections that they could readily adopt without materially impeding covered individuals from getting needed tests. We respectfully request that plans be permitted to implement reasonable pro rata leading and trailing "gates" to manage acquisition, direct coverage, and/or reimbursement coverage for OTC COVID-19 tests.

Plans understand the Departments' approach balancing the accessibility and convenience of being able to acquire or be reimbursed for multiple tests at one time. It is our impression though that there are significant effects from the supply chain deficiencies, supplier limitations, equitable availability, and significant potential for conflict, confusion, and abuse with an open, large time window (a month) and a relatively high limit (8 per person). Some plans may prefer and be able to provide such a wide time and quantity allowance, and should be permitted to do so. In fact, as illustrated in the FAQs, plans are free to provide coverage for more than 8 tests per person per month and some may do so. Some plans may also be unable to establish reasonable controls and will simply absorb unnecessary costs and exposure to meet the required minimums. However, plans that are able should be permitted to adopt reasonable controls within the month (or 30 day period) aimed at ensuring tests are available to their covered individuals when needed, while also remaining available for the public at large, and guarding against fraud and abuse.

We expect some consumer confusion, a potential "rush" for "free tests" accompanied by some disappointment, frustration, and even anger with unavailability or delays as these requirements become effective. We believe plans can play a helpful and constructive part in ensuring that tests are available while tempering expectations and not causing people to be frustrated with either the plan or the retailer or other supplier. Our understanding is that many retailers have set limits in the number of tests an individual can obtain at one time in order to support wider distribution needs. Reasonable gating and plan limitations within the month and 8-test standard (e.g., 2 tests per person per week) that align with these types of retail limitations help alleviate a misimpression that any one actor among the stakeholders is "the problem." People are accustomed to various retail and plan limitations and managing their individual needs in light of reasonable, well-formed and communicated controls. We believe allowing plans to control the "flow" of coverage, including direct coverage or reimbursement, of tests in amounts fewer than 8 per person and in a time period of less than a month (or 30 days) at a time is prudent, reasonable, in-line with avoiding fraud, waste, and abuse, and promotes equitable availability of tests.

Relatedly, the overarching objective of the requirement is to ensure that people are able to get tests *when they need tests*. We expect that people will seek to acquire tests at the time they need them or before they need them. Once a period of time has elapsed without someone needing or acquiring tests that they could have acquired during that time, had they needed, expected to need, or desired them, it is prudent for continued stability, availability, and control of fraud and abuse, to "close" the coverage applicable to tests that would be "credited" to that time. For example, if an individual

does not have or anticipate any need for OTC tests for February and does not acquire any tests, the plan should not be required to cover an allotment of 8 tests that individual procures later but "attributes" to February. Additionally, within February, the plan should be able to close each week as it passes without the individual having needed or acquired a test so that on February 28, the individual has access to test coverage, but in some amount less than the full 8. Leaving a month "open" for all 8 tests at any time during the month, we believe does not maximize a needs-based approach that is so vital in this time of low inventory and equitable distribution challenges. It leaves open the possibility of stockpiling tests by those fortunate enough not to have needed them in a past or passing period.

For the reasons provided above, we urge the Departments to allow plans to implement reasonable pro rata intra-month leading (up-front limits) and trailing (once a period has passed) "gating" limitations on any rational basis for all types of coverage, including reimbursement, direct coverage, or direct provision of tests.

Thank you for your consideration. We would welcome the opportunity to discuss these comments or any other matters impacting employer plan sponsors. Please feel free to contact me (kelsay@businessgrouphealth.org) or Garrett Hohimer, Director, Policy and Advocacy (hohimer@businessgrouphealth.org) to discuss further.

Sincerely,

Ellen Kelsay
President and CEO