Annual Report on the Changes in the Affordable Care Act on Maryland

MSAR #12765

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Maryland Insurance Administration
Maryland Health Benefit Exchange
Health Education and Advocacy Unit – Office of the Attorney General

Introduction

During the 2020 Legislative session, Senate Bill 872 (Ch. 621) / House Bill 959 (Ch. 620) - Health Insurance - Consumer Protections passed the General Assembly. This bill established a new subtitle in the Insurance Article and incorporated consumer protection provisions of the federal Patient Protection and Affordable Care Act (ACA) that were specified through cross-references in Maryland law, and also established nondiscrimination provisions. The bill requires the Maryland Insurance Administration (MIA), the Health Education and Advocacy Unit (HEAU) of the Office of the Attorney General, and the Maryland Health Benefit Exchange (MHBE) to (1) monitor federal statutes and regulations to determine whether provisions of the ACA or corresponding regulations are repealed or amended to the benefit or detriment of Maryland consumers and (2) by December 31 each year until 2024, submit a specified joint report to the Senate Finance Committee and the House Health and Government Operations Committee.

The MIA, HEAU, and MHBE specifically focused on the 2019 Exchange Program Integrity final rule, the 2021 Notice of Benefit and Payment Parameters Final Rule, the Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority Final Rule, and the Families First and CARES Acts as they relate to COVID-19 testing and vaccines. The Consolidated Appropriations Act, 2021 (H.R. 133) is not addressed.

2019 Exchange Program Integrity Final Rule

On December 27, 2019, the U.S. Department of Health and Human Services (HHS) issued the final rule *Patient Protection and Affordable Care Act; Exchange Program Integrity* (84 Fed. Reg. 71674) on exchange program integrity that changes the way that insurers must bill, and consumers must pay, for certain abortion services in qualified health plans. Under the rule, insurers must send, and consumers must pay, two separate monthly bills for the amount of the premium attributable to non-Hyde abortion services and the amount of the premium for all other services (45 CFR 156.280(e)(2)(ii) and (iii)). Separate paper bills may be included in the same envelope or mailing. Separate electronic bills must be sent in separate emails or electronic communications. Insurers must instruct the enrollee to pay the bills in separate transactions and make reasonable efforts to collect the payment separately. The rule made these requirements effective with the first billing cycle following June 27, 2020.

On May 8, 2020 CMS published the interim final rule *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program* (85 FR 27550). In this rule, CMS announced a 60-day extension from the original deadline of June 27, 2020 for implementation of the billing and payment requirements previously described, citing a need for QHP issuers and exchanges to devote resources to respond to the COVID-19 emergency. CMS also announced a non-enforcement policy that would delay enforcement to: 1) one year after the regulation was published (Dec 2019), or 2) six months after the federal emergency ends, whichever is later.[1] No insurers participating with MHBE have implemented the abortion billing requirements.

California, Maryland and other states, on January 30, 2020, challenged the HHS final rule relating to separate premium billing for abortion coverage. On July 20, 2020, Judge Laurel Beeler granted the states' motion for summary judgment and set the rule aside. The court found that the rule was arbitrary and capricious because the Administration did not advance a reasoned explanation for deviating from its prior rule and industry practice. Judge Beeler's decision follows a similar ruling issued by the District of

[1] https://www.federalregister.gov/d/2020-09608/p-551.

Maryland's Judge Catherine Blake on July 10, 2020, in *Planned Parenthood of Maryland, Inc., et al. v. Azar et al.*, No. 1:20-cv-00361-CCB (D. Md. July 10, 2020). On September 17, 2020, the United States appealed to the U.S. Court of Appeals for the Ninth Circuit. The Appellant's opening brief is due December 28, 2020. It is likely that the Biden administration will repeal the abortion billing requirements before the federal non-enforcement period ends.

No recommendations are being made for the General Assembly to enact legislation in relation to these billing requirements at this time.

Changes to ACA Regulations via 2021 Notice of Benefit and Payment Parameters Final Rule

On May 14, 2020, the HHS published the 2021 Notice of Benefit and Payment Parameters (NBPP) Final Rule. The NBPP is published annually to make updates to rules and regulations governing the implementation and enforcement of the ACA. The MIA, HEAU and MHBE focused on certain provisions of the NBPP outlined below.

Revisions to Special Enrollment Periods – 45 CFR §155.420

HHS adopted several changes to the regulations governing special enrollment periods (SEPs) through the 2021 NBPP. HHS routinely uses the annual NBPP to clarify or add to the situations in which a qualified individual can obtain a SEP in response to changes in the market or a change in consumer circumstances, etc. Most of these regulatory changes are effective for 2021, but one was delayed to 2022.

A. New plan options for certain enrollees eligible for a SEP at 45 CFR §155.420(a)(4)(ii)(B) to allow enrollees in a Silver-level qualified health plan (QHP) who become newly ineligible for cost-sharing reductions (CSRs) to change to a QHP one metal level higher or lower (85 FR 29205; 85 FR 29260)

    - Effective in 2022 to allow Exchanges and carriers more time to implement the change
    - Under current rules at §155.420(a)(4)(iii)(A), enrollees who become newly ineligible for CSRs can change to another QHP within the same metal level unless there is no other QHP available at that metal level, in which case enrollees may enroll in a QHP one metal level higher or lower (85 FR 29205)
    - Current rules at §147.104(b)(2)(iii) will continue to allow an enrollee who qualifies for this SEP to purchase off-Exchange coverage without limitation to the metal level (85 FR 29205)
    - Implemented out of concern enrollees in Silver QHPs who lose eligibility for CSRs may not be able to afford cost-sharing for a Silver plan (85 FR 29205)

B. New plan options for certain qualified individuals eligible for a SEP at 45 CFR §155.420(a)(4)(iii)(C) allow a non-enrolled qualified individual who qualifies for an SEP and has dependent(s) who is/are enrolled in a QHP to add self to that plan, enroll self and dependents in a QHP one metal-level higher or lower, or enroll in any separate QHP (85 FR 29206).

    HHS stated existing rules did not explicitly address all situations in which a current enrollee is a dependent of a qualified individual who is newly enrolling in Exchange coverage through a SEP. For example, HHS stated it is unclear what limitations apply when a mother loses her self-only employer-sponsored coverage, thereby gaining eligibility for a SEP for loss of minimum essential coverage, and seeks to be added as an enrollee to the Exchange coverage in which her two

children are currently enrolled. This new SEP is intended to address situations such as this (85 FR 29206).

Concerns were raised that enrollees changing plans mid-coverage year might not realize that their out of pocket costs could increase if their deductibles and other accumulators reset. HHS acknowledged the concern and noted that HHS does allow insurers the option to preserve or reset progress towards accumulators for enrollees who switch plans mid-year. Maryland law is silent on this.

C. Existing SEP at 45 CFR §155.420(d)(1)(ii) related to loss of coverage under non-calendar year plans was revised to include as eligible for a SEP individuals and dependents offered or enrolled in a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) (85 FR 29210; 85 FR 29260).

At this time, the MIA, HEAU and MHBE agree that no legislation is needed to address these amendments because existing Maryland law already gives the MIA and MHBE the authority to enforce these federal SEPs and associated effective dates.

Termination of Coverage for QHPs – 45 CFR §155.430 and 45 CFR §156.270

A. 45 CFR §155.430(d)(9) was revised so that retroactive terminations in the event of a technical error that prevented termination from Exchange coverage will be retroactive to the date the enrollee can demonstrate to the Exchange the enrollee originally attempted to terminate coverage, as opposed to no sooner than 14 days after the date the enrollee can demonstrate they contacted the Exchange to terminate coverage (85 FR 29211; 85 FR 29261).

B. 45 CFR §156.270(b) was revised to require a carrier to send a termination notice to enrollees for all termination events described in 45 CFR §155.430(b), regardless of who initiated the termination (85 FR 29238; 85 FR 29262).

The former rule change is beneficial to Maryland consumers as it ensures enrollees who suffered technical errors in their attempt to terminate Exchange coverage are placed in the same position in which they would have been absent the technical error. The latter rule change is also beneficial as it increases transparency in the event of termination.

At this time, the MIA, HEAU and MHBE agree that no legislation is needed to address these amendments because QHP terminations are administered by MHBE, and MHBE has the authority to promulgate regulations to implement the federal requirements.

Direct Support from Drug Manufacturers (Drug Coupons) – 45 CFR §156.130(h)

HHS revised the wording of 45 CFR §156.130(h)[2] to clarify a carrier may, to the extent permitted by state law, count towards an enrollee's out-of-pocket maximum any form of direct support, i.e. "discount cards," manufacturer coupons, etc. offered by prescription drug manufacturers. Further, carriers must be transparent regarding how they will treat direct support in their plan and marketing materials (85 FR 29230, 29232, 29234).

Until plan year 2020, ACA regulations were silent on the issue of the impact of direct support on enrollees' out-of-pocket maximums. However, the 2020 NBPP, published on April 25, 2019, temporarily

[2] 84 Federal Register 80 at 17567-8; https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf

adopted a regulation that specified a carrier may choose to count or exclude direct support from an enrollee's out-of-pocket maximum when an enrollee selects a brand name drug for which a medically appropriate generic equivalent is available. In issuing the regulation, HHS recognized that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients, but noted that the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. HHS posited that, "when consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true costs of drugs. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs." Balancing those concerns with those of patients needing access to medications, HHS also noted that that when there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market. The regulation as published raised significant questions as to if carriers were *required* to count direct support towards an enrollee's out-of-pocket maximum in other circumstances, i.e. for a brand name drug for which a medically appropriate generic equivalent is not available.[3]

Due to substantial national confusion expressed by state regulators, and a potential conflict with IRS requirements for HSA-compatible high deductible health plans, HHS announced on August 26, 2019, that the federal government would not be enforcing the provision in the 2020 NBPP relating to direct support offered by drug manufacturers, and would revisit the issue in the 2021 NBPP.

In revising this regulation in the 2021 NBPP, HHS clarified stakeholder concerns and left decisions on how to treat direct support to carriers and state law.

Maryland law does not currently address this issue, meaning each carrier may determine how it will handle the issue of direct support, when such action is consistent with other applicable laws and rules (e.g. HIPAA and non-discrimination requirements). Consumers and consumer advocates have expressed serious concerns to the MIA and HEAU that carrier requirements excluding direct support from counting towards a member's out-of-pocket costs are harmful as direct support allows some enrollees to access high-cost, medically necessary prescription drugs through their plan's prescription drug benefit that they may not otherwise have accessed due to deductible, coinsurance, or copay amounts. There have also been complaints in recent years that carriers added contract terms which exclude drug manufacturer coupons from applying to an enrollee's annual limits on out-of-pocket costs are non-transparent, vague, and sometimes incorporated into contracts without proper notice.

In response to the latter concern, MHBE mandated in its 2021 Letter to Issuers Seeking to Participate in Maryland Health Connection that carriers shall disclose in their "Important Information About This Plan" document if they use a copay accumulator program for prescription drugs covered in their formulary. Issuers must also provide information on how the program may impact enrollees' out-of-pocket costs. This has resulted in increased transparency in plans offered through the Exchange.

Four states – Arizona, Illinois, Virginia, and West Virginia – have passed laws that limit or prohibit copay accumulator programs, according to Ben Chandhok, senior director of state legislative affairs at the Arthritis Foundation.[4] Seventeen states considered similar bills in 2020.[5]

[3] 85 Federal Register 94 at 29261; 45 CFR § 156.130 (h)

[4] https://khn.org/news/2021-health-plans-granted-leeway-to-limit-consumers-benefit-from-drug-coupons/.

[5] *Id.*

The MIA, HEAU and MHBE recommend the General Assembly consider legislation to best address the needs of Marylanders and direct the General Assembly to a 2020 Report to the Massachusetts Legislature titled "Prescription Drug Coupon Study." (https://www.mass.gov/doc/prescription-drug-coupon-study/download)

Section 1557 of the Patient Protection and Affordable Care Act (ACA); Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160 (June 19, 2020) (the Final Rule)

ACA Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, disability, and age in a broad range of health programs and activities. In 2016, HHS promulgated a final rule, developed over the course of six years, to implement the nondiscrimination requirements of Section 1557. The 2016 rule specifically defined sex to include discrimination on the basis of gender identity and sex stereotyping, among other criteria. On June 19, 2020, HHS published a new rule, 85 Fed. Reg. 37,160 (June 19, 2020) (2020 Rule or Rule), rescinding most of the 2016 Rule's core provisions and amended other HHS regulations unrelated to Section 1557, reversing anti-discrimination protections that prohibit discrimination on the basis of race, color, national origin, disability, sex, and age. The 2020 Rule was published days after the June 15, 2020, Supreme Court decision, *Bostock v. Clayton County, Georgia*, which held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." The Final Rule rolls back the 2016 rule and limits the protections for LGBTQ people, among others. The Final Rule would permit discrimination in our healthcare system by narrowing the scope of the statute's protections, exempting entities that are subject to Section 1557. It also eliminates important definitions of discrimination, opening the door to discriminatory treatment based on gender identity, sex stereotyping, and pregnancy termination.

During Maryland's 2020 legislative session, in the face of legal challenges to the ACA in *Texas v. United States*, and the proposed roll back of the antidiscrimination protections, this body enacted legislation to expand Maryland's antidiscrimination protections to specifically prohibit 1) hospitals, related institutions and licensed healthcare providers from refusing, withholding from, or denying any individual with respect to their medical care because of the person's race, color, religion, sex, age, national origin, marital status, sexual orientation, gender identity, or disability, 2020 Md. Laws Ch. 428 (H.B.1120); and 2) carriers from excluding consumers from participation in, denying benefits to, or otherwise subjecting consumers to discrimination because of the person's race, sex, creed, color, national origin, marital status, sexual orientation, age, gender, gender identity, or disability, 2020 Md. Laws Ch. 621 (S.B.872).

On July 20, 2020, the Attorney General joined a multistate suit filed in the Southern District of New York that challenges the legality of the federal June 2020 Final Rule. That litigation is in the motions stage, but in a similar case in the District Court for the District of Columbia, *Whitman-Walker Health v. HHS*, on September 2, 2020, Judge Boasberg issued an order preliminarily enjoining parts of the 2020 Rule. HHS will be preliminarily enjoined from enforcing the repeal of the 2016 Rule's definition of discrimination "[o]n the basis of sex" insofar as it includes "discrimination on the basis of . . . sex stereotyping." (81 FR 31467) In addition, the agency will be preliminarily enjoined from enforcing its incorporation of the religious exemption contained in Title IX. See 45 C.F.R. § 92.6(b). On October 31, 2020, the Defendants appealed Judge Boasberg's September 2 Order to the United States Court of Appeals for the District of Columbia Circuit.

The Families First and CARES Acts mandate coverage of costs related to testing for COVID-19 and vaccines

Through passage of the Families First Act[6] and the CARES Act,[7] Congress amended the ACA to mandate private[8] and public[9] insurance coverage, with few exceptions,[10] of COVID-19 testing and related items and services without cost sharing or medical management requirements.[11] Congress mandated the same coverage, and also provided funding, for the testing of uninsured individuals.[12] Vaccine coverage is mandated subject to the same exceptions.[13]

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[6] FAMILIES FIRST CORONAVIRUS RESPONSE ACT, PL 116-127, March 18, 2020, 134 Stat 178 ("Families First Act")

[7] CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT, PL 116-136, March 27, 2020, 134 Stat 281 ("CARES Act")

[8] SEC. 6001. COVERAGE OF TESTING FOR COVID–19. (d) TERMS.—The terms ''group health plan''; ''health insurance issuer''; ''group health insurance coverage'', and ''individual health insurance coverage'' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), section 733 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code of 1986, as applicable. Families First Act, 134 Stat 201. Families First Act, 134 Stat 202.

[9]The Families First Act mandates coverage with no cost sharing for enrollees in Medicare, Medicare Advantage, Medicaid and CHIP plans in Sections 6002 through 6004. 134 Stat 203-207.

[10] Short-term, limited-duration insurance is expressly excluded from the definition of health insurance under the ACA, and is not covered by the Families First Act or the CARES Act; excepted benefits are likewise not covered, Section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91(b)(5) and (c)).

[11] SEC. 6001. COVERAGE OF TESTING FOR COVID–19. (a) IN GENERAL. [Health plans] shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period[]:
(1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products.
(2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product. Families First Act, 134 Stat 201.

SEC. 3201. COVERAGE OF DIAGNOSTIC TESTING FOR COVID-19. Paragraph (1) of section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116-127) is amended to read as follows:
``(1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, and the administration of such a test, that—"
(A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3);``
(B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;``
(C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID-19; or``
(D) other test that the Secretary determines appropriate in guidance." CARES Act, 134 Stat.366-67.

[12] In the Families First Act, Congress appropriated $1 billion to cover costs related to testing of uninsured individuals, defined as an individual not enrolled in (1) a federal health care program or (2) an ACA-compliant private health insurance plan. 134 Stat. 182.

[13] SEC. 3203. RAPID COVERAGE OF PREVENTIVE SERVICES AND VACCINES FOR CORONAVIRUS. (a) [Health plans shall] cover (without cost-sharing) any qualifying coronavirus preventive service…. (b) Definitions.--For purposes of this section: (1) Qualifying coronavirus preventive service.--The term "qualifying coronavirus preventive service"' means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 and that is--(A) an evidence-based item or service that has in effect a rating of ``A" or ``B" in the current recommendations of the United States Preventive Services Task Force; or (B) an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved. CARES Act, 134 Stat. 367-68.

The Families First Act and the CARES Act are in effect through the period of the federal public health emergency, currently set to expire January 20, 2021, unless an earlier termination date is announced, or a further extension is granted.[14]

The General Assembly granted the Governor discretion to authorize similar coverage provisions for testing and vaccines in emergency legislation that went into effect March 19, 2020, and expires April 30, 2021 unless extended.[15] Topics that may warrant further legislative action during the 2021 Session are the duration and scope of insurance coverage of vaccines and COVID-19 testing and related items and services without cost sharing or medical management requirements.

The Families First Act and the CARES Act broadly define and cover diagnostic testing. The broad scope derives from incorporation into those laws of the FDA's regulatory definition of "in vitro diagnostic products" as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health**,** in order to cure, mitigate, treat, or prevent disease or its sequelae."[16] Tests for active infection (molecular PCR tests that detect the virus's genetic material and antigen tests that detect specific proteins from the virus) and tests for past infection (serology tests that detect antibodies) would appear to fall within the broad definition.[17] CMS however has issued guidance that "testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of "mandated coverage."[18] Members of Congress reacted to the guidance by stating, in part, that "the Administration's revised guidance [is] deeply concerning as it appears to be a change that is without basis in the plain language of the statute."[19]

Maryland law is not clear, expressly or in application, to consumers, employers, carriers, providers or sellers of direct to consumer (DTC) products, about the scope of mandated coverage. Questions have been raised about the following, for example:

(1) In the Secretary of Health's 2020-12-01 Amended Directive and Order Regarding Various Healthcare Matters, the Secretary directs that healthcare providers shall order a COVID-19 test for any individual who believes it necessary, regardless of symptoms, but recommends that individuals contact their health plan prior to receiving a COVID-19 test to determine whether testing is covered by the plan in

[14] https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx

[15] COVID-19 Public Health Emergency Protection Act of 2020, 2020 Maryland Laws Ch. 14 (effective March 19, 2020)("Emergency Protection Act")

[16] 21 C.F.R. § 809.3(a)

[17] https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics , Coronavirus Disease 2019 Testing Basics (as of November 6, 2020)

[18] https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf , Q5, FAQSs About Families First Coronavirus Response Act And Coronavirus Aid, Relief, And Economic Security Act Implementation Part 43 (issued June 23, 2020).;

[19] July 7, 2020 Congressional letter to the Departments about the FAQs: "We believe this guidance is contrary to statute, and urge you to take immediate action to clarify the obligations of group health plans and insurers to provide robust and comprehensive coverage of COVID-19 testing. … We find the Administration's revised guidance deeply concerning as it appears to be a change that is without basis in the plain language of the statute. The requirement that the testing be "primarily intended for individualized diagnosis or treatment of COVID-19" was not included in the statutory language of the Families First Act and the CARES Act. This interpretation of the Families First Act is not supported by the statute, which makes clear that health plans are required to cover, without any conditions or limitations, the specified items and services related to diagnostic tests for the detection of COVID-19."
https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/HHS.DOL_.DOT_.2020.7.7.pdf

their circumstance. The order further states that out-of-pocket expenses may apply if the test is not covered by the health plan.

(2) At home sample collection kits**.** The FDA has issued Emergency Use Authorizations (EUAs) for prescription only, at home sample collection kits since April 2020.[20] According to a Maryland consumer who filed a complaint with the HEAU, as well as the company's website, QuestDirect (owned by Quest Diagnostics) refuses to provide DTC purchasers "the information generally required by health plans for reimbursement."[21] As a result, the consumer has been unable to obtain reimbursement from her plan for the cost of the product.

(3) At home complete test kits. On November 17, 2020, the FDA issued an EUA for the first molecular test that can be fully self-administered and provide results at home.[22] It is prescription only and currently available only for use in providers' offices.[23] By the second quarter of 2021, the manufacturer expects DTC sales at a cost of $50 per test.[24] Consumer demand is expected to be high. The manufacturer's website does not state whether it will provide consumers the information generally required by health plans for reimbursement.

(4) Rapid antigen tests. Anecdotally, the HEAU is hearing about providers requiring consumers to pay out of pocket, up-front, for rapid antigen tests.

As of August 2020, six states - California, Massachusetts, New Jersey, New York, Rhode Island, and West Virginia — require state-regulated insurers to cover the cost of asymptomatic testing for certain workers or individuals, but these laws do not apply to federally regulated self-funded employer plans.[25] All stakeholders in Maryland would benefit from clear information about what testing is covered at no-cost to consumers and for what purposes, especially given the expanding recommendations for consumers to get tested for myriad public health surveillance reasons.

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[20] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection#:~:text=Once%20patients%20self%2Dswab,at%20the%20present%20time. Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection (April 21, 2020)

[21] https://questdirect.questdiagnostics.com/products/covid-19-active-infection/2713afd8-3d0c-4819-b877-6880a776cc46 , COVID-19 Active Infection, starting at $119 plus $9.30 physician fee (accessed November 24, 2020)

[22] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home , Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home (November 17, 2020)

[23] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home; https://2nyvwd1bf4ct4f787m3leist-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/FDA-Authorizes-First-Prescription-At-Home-Molecular-Test-for-COVID-19-released-20201118.pdf

[24] *Id.*

[25] https://www.commonwealthfund.org/blog/2020/asymptomatic-covid-19-testing-essential-workers