Nebraska Law Review

Volume 102 | Issue 2 Article 4

2023

Masking Vulnerability: Including PPE as a Covered Service in Health Insurance

Mary Leto Pareja
University of New Mexico School of Law, mpareja@law.unm.edu

Mary Leto Pareja*

Masking Vulnerability: Including PPE as a Covered Service in Health Insurance

ABSTRACT

The COVID-19 pandemic laid bare the shared vulnerability inherent in the human condition, prompting a collective recognition of our physical susceptibility to infectious diseases. While great strides have been made in combating COVID-19 through vaccinations and treatments, a portion of the population remains profoundly vulnerable due to health conditions that make the disease more dangerous, that limit vaccine efficacy, or that prevent vaccination altogether.

This article explores a path forward by proposing a solution within health benefit plans—encompassing both private health insurance and public health benefits. Specifically, the article advocates for a coverage mandate for over-the-counter personal protective equipment (PPE) at zero out-of-pocket cost for vulnerable individuals. Drawing on the experiences of those facing heightened susceptibility, such as immunocompromised patients undergoing chemotherapy, the article highlights the critical role of PPE in safeguarding against infectious diseases.

The article proceeds with a comprehensive exploration, beginning with a background on infectious diseases and the context of COVID-19. It then scrutinizes the current landscape of health benefit plans and their coverage of personal protective equipment. The proposal is systematically presented, detailing how a mandate can be structured to

* Professor of Law, Pamela B. Minzner Chair in Professionalism, University of New Mexico School of Law; Smith College, B.A., 1991; Georgetown University Law Center, J.D., 1996. I am grateful to Professors Nathalie Martin and Sarah Steadman for their insightful and helpful comments, and Hannah Shotwell for superb research assistance. I am also grateful to the University of New Mexico School of Law, the Don L. and Mabel F. Dickason Professor fund, and the Pamela B. Minzner Chair fund for their financial support of this project. Opinions expressed in this article are solely mine, as are any mistakes or omissions.

implement comprehensive coverage and including an exploration of different design elements that could be utilized to broaden or narrow the coverage mandate.

The article advocates for a paradigm shift in health benefit plans to address the ongoing vulnerability faced by a segment of the population. By mandating zero out-of-pocket costs for PPE, this proposal aims to empower vulnerable individuals to protect themselves against infectious diseases. In doing so, it seeks to bridge the gap in current health coverage and foster a more inclusive and resilient healthcare system in the post-pandemic era.

TABLE OF CONTENTS

I. INTRODUCTION

A commonality of the human condition is our physical vulnerability. We are not all equally vulnerable, but we are all physically vulnerable at times. Human beings that can experience empathy should recognize

this fundamental truth, even if it is not always as salient as it could be. For many of us, our fundamental physical vulnerability is not at the forefront of our minds—it is simply not something we think about much as we go about our day-to-day activities. Many of us are privileged enough to be healthy and have enough social resiliency to weather a physical setback. In other words, many of us do not actively feel vulnerable even though we are. The COVID experience carried with it an important lesson about vulnerability. It taught us, if we did not already know it, what it feels like to be intensely physically vulnerable.

The world experienced a shared vulnerability as it faced the COVID pandemic. COVID was a novel virus. In the early days of the pandemic, we were all vulnerable because none of our bodies knew how to fight it, and we simply did not know enough about the virus to assess relative risks. We now know that we were not equally vulnerable. During the initial spread of COVID, almost all of us took steps to protect ourselves and our families from a vast unknown. The Author isolated her newspaper and mail for three days before opening it and wiped down potato chip bags with precious Clorox wipes. A friend of the Author changed their clothes in the garage after being obligated to venture into the "outside world."

This feeling of intense vulnerability has mostly passed thanks to vaccines, new treatments, and a better scientific understanding of this disease. There is no doubt that the COVID situation is better overall; case counts, hospitalizations, and deaths are all down dramatically.[1] The overall situation has improved so much that the United States lifted its public health emergency declaration on May 11, 2023.[2] However, there are many people who are still intensely vulnerable to COVID, as well as to other diseases. People who cannot receive a vaccine. People for whom a vaccine is far less effective because of underlying health conditions. People who are contraindicated from COVID treatments. They all remain vulnerable.

With a shared experience of intense vulnerability as a backdrop, this Article explores a path to help address the needs of those still experiencing vulnerability. This Article proposes that health benefit plans, including private health insurance and public health benefits,

1. Letter from Xavier Becerra, Sec'y, U.S. Dep't Health & Hum. Servs., to U.S. Governors (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html [https://perma.cc/3U7E-N8JG] (noting that "since the peak of the Omicron surge at the end of January 2022: Daily COVID-19 reported cases are down 92%, COVID-19 deaths have declined by over 80%, and New COVID-19 hospitalizations are down nearly 80%.").

2. *Id.*; *see* Alex Azar, *Determination That a Public Health Emergency* Exists, U.S. DEP'T HEALTH & HUM. SERVS., (Jan. 31, 2020), https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx [https://perma.cc/97K8-9MVA] (providing that then Secretary of Health and Human Services, Alex Azar, declared COVID-19 a public health emergency under Section 319 of the Public Health Service Act).

cover cost over-the-counter personal protective equipment that vulnerable individuals can use to protect themselves against infectious disease at zero cost out-of-pocket.

A couple of anecdotes illustrate how meaningful such a change could be. The Author's father-in-law was diagnosed with pancreatic cancer in November 2022 and began chemotherapy shortly before Christmas. His oncologist explained to him how the chemotherapy would effectively destroy his immune system and how important it was to avoid infections that his body would be increasingly unable to combat. The oncologist instructed him to drink distilled water and avoid waterborne pathogens, raw or undercooked foods like sushi and raw honey, and large crowds or interacting with people with contagious illnesses. The oncologist further explained to the Author's father-in-law that his county was experiencing a high rate of COVID transmission as well as high levels of influenza and respiratory syncytial virus (RSV) and that it was common for people to be contagious with these illnesses before experiencing any symptoms themselves. The oncologist recommended that the Author's father-in-law wear a respirator-style face mask (an N95 or KN95) when interacting with anyone outside his immediate family. The Author's father-in-law readily agreed to forego Christmas shopping at jam-packed malls and grocery stores, but he was insistent that he wanted to attend the annual Christmas gathering of his extended family. The Author's family is privileged enough to afford to buy high-quality masks. However, the cost of masks is not insignificant and would be a barrier to many individuals. In January 2023, FDA-certified medical N95 masks sold through CovCare ran between $1.48 to $2 per mask, depending on the quantity bought.[3] That amounts to an annual cost of $540.20 to $730 if one uses just one mask per day. KN95 masks are more affordable, ranging between $0.32 to $0.99 per unit.[4] The Author's father-in-law bought high-quality KN95 masks, participated in the family festivities, and avoided infection; he continues to battle cancer.

As another example, National Public Radio (NPR) asked several people it had interviewed throughout the pandemic for their reflections about the official end of the COVID public health emergency.[5] Dr. Vivian Cheung, an immunocompromised patient who is a pediatrician and research scientist, told NPR that she rarely ventures outside

3. *Medical N95 Mask for Sale*, CovCare.com, https://cov.care/medical-n95-facemasks-fda [https://perma.cc/DU2A-PBNU] (last visited Jan. 14, 2023).
4. *Our CE Certified, KN95 Masks For Sale: KN95 Masks in Stock*, CovCare.com, https://cov.care/kn95-facemasks [https://perma.cc/6XWZ-GL8H] (last visited Jan. 14, 2023).
5. Selena Simmons-Duffin, Pien Huang & Rhitu Chatterjee, *Pandemic Hits 'Stop Button,' But for Some Life Is Forever Changed*, NPR (May 11, 2023, 12:40 PM), https://www.npr.org/sections/health-shots/2023/05/11/1175463986/public-health-emergency-ends-people-most-affected-reflect [https://perma.cc/KU5B-WKBK].

of her home except for work, that she is hoping to enroll in clinical trials for a second-generation drug designed to protect immunocompromised individuals against COVID, and that face masks have always been part of her daily routine.[6] NPR reports that Dr. Cheung "thinks the pandemic raised people's awareness of disabilities and vulnerabilities, but worries that grace and understanding is fading."[7] Dr. Cheung's experience illustrates the role that access to personal protective equipment can play in helping individuals address their personal vulnerabilities to illness.

Part II of this Article provides relevant background information regarding the science of infectious disease and the context of COVID-19. Part III of this Article examines the extent to which health benefit plans currently provide access to personal protective equipment to help vulnerable individuals and proposes that these plans can be amended to provide greater access. Part IV of this Article explores how one could design a mandate to implement the proposal could be designed. Part V of the Article is the conclusion.

II. THE SCIENCE BEHIND COMBATTING INFECTIOUS DISEASE

This Article recommends an additional tool that the government can use to help protect individuals at heightened risk of contracting an infectious disease.[8] The proposal is rooted in individual health because it would mandate coverage for equipment that individuals would use to help protect themselves. Public health, emphasizing protecting populations, is indirectly implicated because the proposal deals with infectious disease, a major concern for public health authorities. Understanding how infectious diseases work and how they can be combatted is helpful; this Article uses COVID-19 as a context for examining these questions.

While this Article draws heavily on the current COVID context, the proposal is not limited to this particular virus. The world has faced multiple large-scale pandemics. Perhaps the earliest recorded

6. *Id.*
7. *Id.*
8. This Article uses the terms infectious and contagious interchangeably, although the definitions differ. A contagious disease is one that can spread from person to person, while an infectious disease spreads by an infectious agent entering the body. *See* Lauren Smith & Alexandra Schwarz, *Doctor Decoded: Infectious vs. Contagious*, GOODRX HEALTH (June 14, 2022), https://www.goodrx.com/health-topic/infections/doctor-decoded-infectious-contagious [https://perma.cc/XRL2-FZL4]. For example, influenza is both infectious and contagious, while Lyme disease is infectious but not contagious. *Id.* While there can be diseases that are infectious but not contagious, for the vast majority of diseases that would be implicated by the Article's proposal, the terms overlap. *See id.*

pandemic occurred in 430 B.C. during the Peloponnesian War.[9] It was suspected to be an outbreak of typhoid fever, although researchers have not reached a consensus on the exact nature of disease.[10] Other well-known examples are the outbreak of bubonic plague, commonly called the Black Death, that ravaged Europe and Asia in the Middle Ages,[11] the contagion of multiple diseases such as smallpox and measles that decimated Native American populations following first contact with Europeans,[12] and the 1918 influenza, commonly called the Spanish flu, that killed millions worldwide.[13]

One of the latest iterations of pandemic infectious disease is the Coronavirus Disease 2019, or COVID-19.[14] The disease is caused by a novel coronavirus, SARS-CoV-2, which was first identified in Wuhan, China, in December 2019.[15] Coronaviruses are not new to humankind. They were first identified in the 1960s and take their name from distinctive crown-like protein spikes.[16] Some coronaviruses cause dangerous illnesses, such as the virus responsible for severe acute respiratory syndrome (SARS), while others are more benign, like the coronavirus

9. Robert J. Littman, *The Plague of Athens: Epidemiology and Paleopathology*, 76 MT. SINAI J. OF MED. 456–57 (2009).
10. *Id.*
11. Kathryn A. Glatter & Paul Finkelman, *History of the Plague: An Ancient Pandemic for the Age of COVID-19*, 134 J. OF AM. MED. 176–81 (2021).
12. CHARLES C. MANN, 1491: NEW REVELATIONS OF THE AMERICAS BEFORE COLUMBUS 102–03 (2005) (providing an estimate from anthropologist Henry F. Dobyns that "disease claimed the lives of 80 to 100 million Indians by the first third of the seventeenth century. All these numbers are at best rough approximations, but their implications are clear: the epidemics killed about one out of every five people on earth."). While disease contributed to the decline of the Native American population, it is important to acknowledge that other factors, such as slavery, forced removal, and genocidal bounty systems, also played a part. *See* ANDRÉS RESÉNDEZ, THE OTHER SLAVERY 15–17 (2016); David Michael Smith, *Counting the Dead: Estimating the Loss of Life in the Indigenous Holocaust, 1492-Present*, *in* PROCEEDINGS OF THE TWELFTH NATIVE AMERICAN SYMPOSIUM 7, 10 (Mark B. Spencer ed., 2018).
13. JARED DIAMOND, GUNS, GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES 202 (1997) ("The greatest single epidemic in human history was the one of influenza that killed 21 million people at the end of the First World War."). The 1918 flu is known as the Spanish flu not because it originated in Spain but because Spanish newspapers were able to freely report about the outbreak because Spain was neutral in World War I. Antoni Trilla, Guillem Trilla & Carolyn Dear, *The 1918 "Spanish Flu" in Spain*, 47 CLINICAL INFECTIOUS DISEASES 668–73 (Sept. 1, 2008). Other European and allied countries were fighting the war, and news about the influenza outbreak was suppressed to avoid damaging the morale of the people and the soldiers. *Id.*
14. *About COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fyour-health%2Fabout-covid-19%2Fbasics-covid-19.html [https://perma.cc/RSG7-3GQ8] (last visited Nov. 4, 2021).
15. *Id.*
16. *Human Coronavirus Types*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/types.html [https://perma.cc/NQ4C-75ZL] (last visited Feb. 15, 2020).

responsible for the common cold.[17] COVID-19 is a disease marked primarily by respiratory symptoms, although some individuals have other types of symptoms, like a loss of taste or smell, diarrhea, or red and swollen toes.[18] COVID-19 has swept the globe and caused widespread illness, death, and economic disruption.[19]

A. Epidemics, Pandemics, and Endemics, Oh My

There are many ways to classify and understand the risks posed by infectious diseases. For example, health experts may classify a disease as an epidemic, a pandemic, or an endemic. These classifications pertain to the geographic reach of a disease and the prevalence of the disease in the community. COVID-19 started as an epidemic in Wuhan, China. An "epidemic" is a disease that affects a large number of people in a particular place—a single community or region or perhaps a single population.[20] The word "outbreak" is generally defined the same as "epidemic," and is often used synonymously, although one can use "outbreak" in the context of disease occurring within a more limited geographic area.[21] COVID-19 became a pandemic when it spread first to other countries and then around the entire globe. A "pandemic" is an epidemic that is widely spread.[22]

A disease is "endemic" when it is a constant presence or threat in a particular place, meaning that the disease is not eradicated and that infection and spread is always possible.[23] The term "endemic" also commonly is used to refer to a disease whose spread can be controlled—in contrast to epidemic or pandemic disease.[24] COVID-19 has not yet become an endemic disease, but it is trending in that direction.[25]

---

17. *About COVID-19*, *supra* note 14.
18. *Id.*; Sandra A. Kemmerly, *The Weird COVID-19 Symptoms*, OCHSNER HEALTH (Jan. 29, 2021), https://blog.ochsner.org/articles/the-weird-covid-19-symptoms# [https://perma.cc/3QX7-QQ5M].
19. *Data Tells the Story on How COVID-19 Is Changing the World*, U.N., DEP'T OF ECON. & SOC. AFFS., https://www.un.org/en/desa/data-tells-story-how-covid-19-changing-world [https://perma.cc/87N8-WQL5] (last visited August 7, 2023).
20. *What's the Difference Between a Pandemic, an Epidemic, Endemic, and an Outbreak?*, INTERMOUNTAIN HEALTHCARE (Apr. 2, 2020), https://intermountainhealthcare.org/blogs/topics/live-well/2020/04/whats-the-difference-between-a-pandemic-an-epidemic-endemic-and-an-outbreak/ [https://perma.cc/GQG9-L8GD].
21. *Lesson 1: Introduction to Epidemiology, Section 11: Epidemic Disease Occurrence*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html [https://perma.cc/LTC7-G8ZR] (last visited Aug. 7, 2023).
22. *What's the Difference Between a Pandemic, an Epidemic, Endemic, and an Outbreak?*, *supra* note 20.
23. *Id.*
24. *Will COVID-19 Become Endemic and What Does That Mean?*, HEALTHLINE (Mar. 16, 2022), https://www.healthline.com/health/what-is-an-endemic#endemic-definition [https://perma.cc/KR6C-24XU].
25. Susan E.W. Spencer, *Is COVID-19 Reaching the Endemic Stage? UMass Chan Virologist Jeremy Luban Weighs In*, UMASS CHAN MED. SCH. (Aug. 17, 2022), https://

Effective eradication of COVID-19 through herd immunity appears highly unlikely.[26] Herd immunity occurs when enough individuals have enough immunity to the disease so that infections are isolated and do not spread within the community.[27] That means that it is likely that COVID-19 will remain a threat, but hopefully, a threat that can be mitigated through containment measures.

B. Modes of Transmission

Infectious diseases can be transmitted in different ways and each disease has distinct transmission methods. Infectious diseases can be transmitted through direct physical contact between an infected person and a non-infected person, through direct contact with infected droplets, through direct exposure to an infectious agent in the environment, through an animal bite, or through placenta or breastfeeding.[28] Infectious diseases also can be transmitted indirectly through biological vectors such as mosquitos that act as intermediate hosts, mechanically when a pathogen is transmitted to a host via an item such as contaminated water, or through airborne aerosolized pathogens.[29]

We now know that COVID-19 can be spread from human to human through airborne transmission—an infected person emits contagious small liquid droplets into the air that are inhaled by a non-infected person.[30] Transmission can also occur when the infected droplets land directly on the non-infected person's nose, mouth, or eyes.[31] Alternatively, a person may contract COVID-19 when they touch a contaminated surface and then touch their nose, mouth, or eyes.[32] While scientists continue to study transmission, the evidence seems to indicate that the primary mode of transmission for COVID-19 is airborne transmission (inhaling aerosolized infected droplets) or direct droplet transmission between two people who are within conversational

---

www.umassmed.edu/news/news-archives/2022/08/is-covid-19-reaching-the-endemic-stage-umass-chan-virologist-jeremy-luban-weighs-in/ [https://perma.cc/R2XZ-2WV9].

26. *Herd Immunity and COVID-19: What You Need to Know*, MAYO CLINIC (Sept. 27, 2022), https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808 [https://perma.cc/542D-U2GB].
27. *Id.*
28. Jean Maguire van Seventer & Natasha S. Hochberg, *Principles of Infectious Diseases: Transmission, Diagnosis, Prevention, and Control*, in 6 INT'L ENCYCLOPEDIA OF PUB. HEALTH (2d ed. 2017).
29. *Id.* at 32–33.
30. *Coronavirus Disease (COVID-19): How Is It Transmitted?*, WORLD HEALTH ORGANIZATION [WHO] (Dec. 23, 2021), https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-covid-19-how-is-it-transmitted [https://perma.cc/8FWS-CVVW].
31. *Id.*
32. *Id.*

distance from each other.[33] Other contagious illnesses have different modes of transmission. For example, Monkeypox seems to require close physical contact with an infected person or a contaminated surface.[34] Respiratory Syncytial Virus (RSV) can be spread in the same ways as COVID-19, but in contrast, the principal mode of transmission of RSV appears to be direct contact with infected respiratory fluids.[35] The modes of transmission impact what measures will be effective to block transmission.

C. Individual and Community Immunity

Immunity typically is the best protection for an individual against an infectious disease. An individual has active immunity to an infectious disease if their immune system can produce a response that will ward off the infectious disease.[36] While a person's innate immune response is important, an adaptive immune response is usually stronger, more rapid and better able to defeat disease.[37] An adaptive immune response occurs when the body has already been exposed to an infectious pathogen and remembers how to fight the infection.[38] There are two ways to acquire active immunity: naturally (through active infection) or vaccination.[39]

When COVID-19 was first detected it was novel, or new, and no one had the antibodies needed to combat the infection. Individuals who contract COVID-19 and survive naturally acquire antibodies for the disease.[40] Their bodies have been exposed to the illness and have learned how to fight it; however, prior infection might not be a complete defense against a second infection.[41] Individuals with antibodies may still become infected, sometimes seriously, but their odds of survival and of less serious illness are greater than if they had no antibodies.[42]

33. *Id.*
34. *Monkeypox*, World Health Organization [WHO] (May 19, 2022), https://www.who.int/news-room/fact-sheets/detail/monkeypox [https://perma.cc/YR3U-AUDT].
35. *Respiratory Syncytial Virus*, Tulane Univ., https://tnprc.tulane.edu/respiratory-syncytial-virus [https://perma.cc/R7VH-YB2S] (last visited May 31, 2023).
36. *Immunity Types*, Ctrs. for Disease Control & Prevention (Sept. 24, 2021), https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm [https://perma.cc/WB7U-N4GU].
37. Seventer & Hochberg, *supra* note 28, at 23–24.
38. *Id.*
39. *Immunity Types*, *supra* note 36. It is also possible to obtain passive immunity, such as the immunity a mother gives to an infant. Ctrs. for Disease Control & Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases 2 (Elisha Hall et al. eds., 14th ed. 2021). Passive immunity can also be obtained through the medical use of biologics, such as the transfusion of blood products that contain the desired antibodies. *Id.* at 5. Passive immunity is immediate but temporary. *Id.* at 2.
40. *Immunity Types*, *supra* note 36.
41. Seventer & Hochberg, *supra* note 28, at 24.
42. *Id.*

Because adaptive immunity, which can occur through prior infection or vaccination, is specific to one pathogenic mutation, it can make an individual's already acquired immunity less effective against later mutations of the disease.[43] Whether the antibodies a person's body already has, through infection or vaccine, will be effective against a mutated version of a disease largely depends on the type and extent of the mutation. Not all infectious diseases produce a strong adaptive immune response. For example, RSV does not produce such a response, meaning that a prior infection with RSV provides little or no protection from a subsequent infection.[44] The first vaccine against RSV was recently authorized (on May 3, 2023) by the FDA for adults ages sixty and older, but vaccines for others remain unavailable.[45] That makes prophylactic measures like using personal protective equipment to block exposure to pathogens particularly important.

Vaccines are another way to achieve active immunity against an infectious disease. A vaccine trains the immune system to combat an infection without the necessity of prior active infection.[46] Vaccines expose a person to a pathogen, or parts of a pathogen, in a safe manner so that the person's body can effectively produce antibodies against the illness when they are later confronted by a "wild" version of the pathogen.

There are different types of vaccines, depending on the method used to produce the immune response. A live, attenuated vaccine contains a live, active virus or bacteria that has been weakened in a lab.[47] Even though weakened, a single dose of a live, attenuated vaccine typically results in an adaptive immune response similar to what would occur from an actual infection with the disease.[48] While safe, it is important to note that mild disease may result from vaccination with a live, attenuated vaccine, and when this occurs it is considered an adverse reaction.[49] Live, attenuated vaccines can also cause serious or fatal disease in individuals with weakened immune systems due to conditions such as leukemia or AIDS.[50] An inactivated virus is not live, cannot

43. *Id.*
44. Laura Lambert et al., *Immunity to RSV in Early-Life*, 5 FRONTIERS IN IMMUNOLOGY 1, 1 (Sept. 29, 2014) ("Immunity to reinfection with a single strain of RSV is, at best, partial; re-infections with antigenically similar strains occur throughout life and through to old age.").
45. *FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine*, U.S. FOOD & DRUG ADMIN. (May 3, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine [https://perma.cc/D5AN-GDTY].
46. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 39, at 1.
47. *Id.* at 4.
48. *Id.*
49. *Id.*
50. *Id.* at 5.

replicate, and cannot cause disease.[51] In a process known as immunogenicity, an inactivated virus vaccine takes a live virus and exposes that virus to a process that inactivates enough of the virus so that it can no longer cause a live infection while retaining the portions of the virus that produce the immune response.[52] Inactivated vaccines may require a series of shots to produce a robust adaptive immune response, and they also may require booster shots as their protection tends to fade over time.[53]

A viral vector vaccine extracts the specific parts, typically a protein or sugar, of a virus that triggers an immune response and inserts those proteins into a different virus that does not cause disease.[54] Because the safe vector virus contains the proteins that an individual would have as a result of a natural infection, the vaccine produces an adaptive immune response.[55] A subunit vaccine extracts the proteins of a virus or bacterium that trigger an immune response and delivers them into the vaccinated person without using a safe virus as a vector.[56]

A nucleic acid vaccine takes a different approach to teaching the body to produce an adaptive immune response. Rather than extracting and delivering a live or inactivated whole virus, or the whole proteins of a virus, a nucleic acid vaccine uses parts of the genetic material—the DNA or mRNA—of the proteins that trigger an immune response.[57] Once inside the vaccinated person's body, the genetic material acts as a set of instructions, allowing the vaccinated person's body to produce the proteins that will produce an adaptive immune response.[58] Nucleic acid vaccines have been under development for a long time, but the first vaccines of this type to receive approval for use in humans were for COVID-19.[59] Like with naturally acquired immune responses from prior infection, virus mutations challenge the ability of a vaccine to produce an effective immune response.

When COVID first emerged in late-2019, there were no vaccines that were effective against it, and no one had natural immunity because it was a novel virus.[60] Approximately one year later, the

51. *Id.*
52. *Id.* at 5–6.
53. *Id.* at 6.
54. *The Different Types of COVID-19 Vaccines*, WORLD HEALTH ORGANIZATION [WHO] (Jan. 12, 2021), https://www.who.int/news-room/feature-stories/detail/the-race-for-a-covid-19-vaccine-explained [https://perma.cc/VEP7-UZ6L].
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. Elie Dolgin, *The Tangled History of mRNA Vaccines*, 597 NATURE 318, 318–24 (2021).
60. *CDC Museum COVID-19 Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 16, 2022), https://www.cdc.gov/museum/timeline/covid19.html [https://perma.cc/BE69-J76W].

first COVID vaccine, manufactured by Pfizer-BioNTech received an emergency use authorization by the United States government, with the first dose outside of a clinical trial being given on December 14, 2020.[61] Other manufacturers received approval for their COVID vaccines shortly thereafter.[62] Throughout the following two years, vaccines became available throughout the United States, with priority given to particular populations like the elderly, healthcare workers, and people with compromised immune systems.[63] In December 2020, vaccines were authorized for use in people age sixteen and older; in May 2021, people ages twelve through fifteen were cleared to receive a vaccine; in November 2021, children between the ages of five and eleven were cleared to be vaccinated; and in June 2022, vaccines were approved for children ages six months and older.[64] In August 2021, the Pfizer BioNTech vaccine became the first to receive full approval from the Food and Drug Administration (FDA) for people ages eighteen and older, an upgrade from its prior emergency use authorization.[65] Additional full FDA approval followed for other manufacturers (including Moderna) and for additional age groups.[66] In August 2022, vaccine manufacturers developed an updated "bivalent" vaccine that contains strains from the original virus as well as mutated versions of the virus.[67] This bivalent vaccine quickly received emergency use authorization, first as a booster and later as a replacement for the initially approved vaccines.[68]

As scientists were developing vaccines, vaccine mandates were considered by governments, school boards, and private companies, with some mandates moving forward, others not being implemented, and

61. *Id.*
62. *Id.*
63. *Id.*
64. *Id.*
65. *Id.*
66. *Id.*
67. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose (August 31, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use [https://perma.cc/XF5P-8PSN].
68. *Id.* (authorizing bivalent boosters for patients as young as age 12); Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups (October 12, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines [https://perma.cc/M2T7-CJWD] (authorizing bivalent boosters for patients as young as age 5); Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines (Apr. 18, 2023), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines [https://perma.cc/94LE-CKES] (removing authorization for the original monovalent vaccines and authorizing use of updated bivalent vaccines for all doses).

some governments opting to ban or limit the reach of vaccine mandates.[69] At the end of 2022, the Center for Diseases Control and Prevention (CDC) estimated that of the United States population five years of age or older, 80.8% have received at least one dose of a COVID vaccine requiring more than one dose and 69% have completed a primary series of a COVID vaccine.[70] Worldwide, 64.45% of the population had completed a primary series of a COVID vaccine.[71] However, vaccination rates vary widely; the World Health Organization shows some countries reporting a fully vaccinated rate approaching 100% and others with a fully vaccinated rate of far below 10%.[72]

If enough people have a strong enough immunity to a disease, a "herd immunity" develops, which keeps individual infections from spreading throughout a community.[73] In essence, if a community has herd immunity, individuals may get infected with a disease, but the disease is unable to spread widely. Infections, thus, are isolated. The method for achieving herd immunity varies from disease to disease. For example, highly contagious diseases, like measles, require more people to be immune in to order to stop transmission.[74] Experts predict that herd immunity will be difficult to achieve for COVID-19.[75]

D. Other Prevention Techniques

Other protection measures become more important in the absence of immunity or in the face of incomplete or ineffective immunity. The types of protection measures that will be effective against any particular disease depend on many different factors: the individual's particular risk factors, the contagiousness of the disease, the prevalence of the disease in the community, the modes of possible transmission. These

69. *State Efforts to Ban or Enforce COVID-19 Vaccine Mandates and Passports*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Dec. 27, 2022), https://nashp.org/state-efforts-to-ban-or-enforce-covid-19-vaccine-mandates-and-passports/ [https://perma.cc/H9P6-Q286].

70. *COVID-19 Vaccinations in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5 [https://perma.cc/Y3F2-A5Q4] (last visited Dec. 29, 2022).

71. *WHO Coronavirus (COVID-19) Dashboard, Table View*, WORLD HEALTH ORGANIZATION [WHO], https://covid19.who.int/table [https://perma.cc/7URU-QSG4] (last visited Jan. 4, 2023).

72. *Id.* For example, on January 4, 2023, United Arab Emirates was showing a fully vaccinated rate of 99% while Yemen was showing a fully vaccinated rate of 2.54%. *Id.*

73. *Herd Immunity and COVID-19: What You Need to Know*, MAYO CLINIC (Sept. 27, 2022), https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808 [https://perma.cc/542D-U2GB].

74. *Id.*

75. *Id.*

secondary measures are designed to prevent a pathogen from entering the body of a non-infected individual.[76]

In the COVID-19 context, "social distancing," which is actually physical distancing, is employed to reduce the risk of transmission.[77] This measure can be effective because the COVID-19 virus can be transmitted when infected droplets land on a non-infected person's eyes, nose, or mouth. Increasing the distance between individuals makes it more difficult for droplets expelled from an infected person to land on someone else.[78] The distance required varies and depends on different factors.[79] For example, the droplets expelled from singing or coughing travel farther than the droplets expelled from whispering or breathing normally.[80] An infected individual can also transmit the COVID-19 virus through the air in aerosolized form.[81] Increasing the physical distance between individuals makes this method of transmission less likely as well, although aerosolized droplets travel further and are harder to avoid by social distancing alone.[82]

Another protection method for COVID-19 is increasing ventilation or avoiding enclosed spaces.[83] Increasing air exchange reduces the likelihood that a non-infected person will inhale infected droplets in the air by dispersing the infected air more broadly.[84] Changing air flow by directing it away from individuals' faces is also helpful.[85] Items like

76. Beverly Merz, *How to Prevent Infections*, HARVARD HEALTH PUBL'G (Feb. 15, 2021), https://www.health.harvard.edu/staying-healthy/how-to-prevent-infections [https://perma.cc/VK5R-5F4Y].
77. Russell H. Fazio et al., *Social Distancing Decreases an Individual's Likelihood of Contracting COVID*-19, 118 PROC. OF THE NAT'L ACAD. OF SCIS. OF THE UNITED STATES OF AMERICA, Feb. 4, 2021, at 1.
78. *See* Chanjuan Sun & Zhiqiang Zhai, *The Efficacy of Social Distance and Ventilation Effectiveness in Preventing COVID-19 Transmission*, 62 SUSTAINABLE CITIES & SOCIETY, July 13, 2020, at 1.
79. *Id.* at 2–4, 6, 8 (explaining that medical, biological, and engineering factors can affect the transmissibility of COVID-19).
80. *Indoor Ventilation: Guidance During the COVID-19 Pandemic*, CANADIAN CTR. FOR OCCUPATIONAL HEALTH AND SAFETY (Jan. 6, 2022), https://www.ccohs.ca/covid19/indoor-ventilation/ [https://perma.cc/D34V-Y3UU].
81. *Id.*
82. *See* Sun & Zhai, *supra* note 78, at 7–8 (providing evidence from studies that suggested aerosolized droplets can travel up to twenty-six feet).
83. *Id.*; *Indoor Ventilation: Guidance During the COVID-19 Pandemic*, *supra* note 80; Hui Dai & Bin Zhao, *Association of the Infection Probability of COVID-19 With Ventilation Rates in Confined Spaces*, 13 BUILDING SIMULATION 1321, 1321 (July 27, 2020).
84. *Ventilation and Coronavirus (COVID-19)*, U.S. ENV'T PROT. AGENCY (June 7, 2023), https://www.epa.gov/coronavirus/ventilation-and-coronavirus-covid-19 [https://perma.cc/85QN-4AB2]; *Ventilation in Buildings*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 12, 2023), https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html [https://perma.cc/TYY8-FYWM].
85. *Ventilation in Buildings*, *supra* note 84.

medical grade air purifiers or UV-C air sanitizers can trap or kill virus particles.[86]

Wearing mouth and nose coverings (masks) is also effective against COVID-19 transmission because masks, when worn correctly, block an infected person from emitting contagious droplets and block a non-infected person from inhaling contagious droplets.[87] The effectiveness of masking varies depending on the type of mask used and how many people in a situation are wearing a mask. For example, an N95 mask offers more protection than a surgical mask, and both are more protective than a cloth mask.[88] Also, studies confirm that masks are effective as both as source control (limiting the pathogens emitted by an infected person wearing a mask) and as inhalation protection (limiting the pathogens inhaled by the wearer of a mask).[89] Thus, while universal or broad mask wearing is the most protective, so-called one-way masking—when a mask is used as personal protective equipment to protect the wearer—can be an important intervention.

Individuals can employ other protective measures to prevent a COVID-19 infection, like frequent, thorough hand washing and using gloves, both of which can help prevent the transmission of pathogens from surfaces to the eyes, nose, or mouth.[90] Other diseases have different protective measures that might be effective against that particular disease. An effective protective measure for one individual might not be as effective for another person. For example, a person who is extremely immunocompromised may need multiple layers of measures

86. *Air Cleaners, HVAC Filters, and Coronavirus (COVID-19)*, U.S. ENV'T PROT. AGENCY (July 7, 2022), https://www.epa.gov/coronavirus/air-cleaners-hvac-filters-and-coronavirus-covid-19 [https://perma.cc/K56X-UNAT].

87. *See* Kristin L. Andrejko et al., *Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection—California, February-December 2021*, 71 MORBIDITY & MORTALITY WEEKLY REP. 212, 213 (Feb. 11, 2022). It is important to note that studies of mask effectiveness in community settings, as opposed to healthcare settings, have sometimes been inconclusive, and that research is ongoing. *See* Jingjing Nie et al., *Need for More Robust Research on the Effectiveness of Masks in Preventing COVID-19 Transmission*, FUTURE VIROLOGY (Mar. 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9017682/.

88. *How Well Do Face Masks Protect Against COVID-19*, MAYO CLINIC (Mar. 1, 2022), https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-mask/art-20485449 [https://perma.cc/FM3F-LRHR].

89. Yuxin Wang, Zicheng Deng & Donglu Shi, *How Effective Is a Mask in Preventing COVID-19 Infection*, MED. DEVICES & SENSORS, Feb. 2021, at 9; Jeremy Howard et al., *An Evidence Review of Face Masks Against COVID-19*, PROC. OF THE NAT'L ACAD. OF SCIS. OF THE UNITED STATES OF AMERICA, Jan. 11, 2021, at 9.

90. *Handwashing an Effective Tool to Prevent COVID-19, Other Diseases*, WORLD HEALTH ORGANIZATION [WHO] (Oct. 15, 2020), https://www.who.int/southeastasia/news/detail/15-10-2020-handwashing-an-effective-tool-to-prevent-covid-19-other-diseases [https://perma.cc/K7YY-S6DR]; *Does Wearing Gloves Protect Against or Stop the Spread of COVID-19?*, HEALTH DESK (May 12, 2020), https://health-desk.org/articles/does-wearing-gloves-protect-against-or-stop-the-spread-of-covid-19 [https://perma.cc/9GEN-LP96].

or may need completely different measures than someone who is not immunocompromised. If levels of disease are very high in a community, additional protective measures may be necessary to provide effective protection for an individual. These protective measures are very important public health tools to combat and control disease at a population level. But they are critically important individual measures as well.

III. SOURCES OF HEALTH COVERAGE AND WHAT HEALTH COVERAGE PROVIDES

This Article proposes that health benefit plans should be required to cover at zero out-of-pocket cost over-the-counter personal protective equipment that vulnerable individuals can use to protect themselves against an infectious disease. Part III examines sources of health coverage and how to implement the proposed mandate.

A. The Federal Income Tax Code: Definition of Medical Care

An expense must be incurred for "medical care" in order to be tax deductible, to be reimbursable under a flexible spending account or health savings account, or to be eligible to be a covered service in an employer health plan.[91] Internal Revenue Code (hereinafter "Code") section 213(d) defines "medical care," in relevant part, as "amounts paid . . . for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body . . . ."[92] Personal protective equipment used by an individual to avoid contracting an infectious disease directly meets this definition as an "amount paid" for the "prevention of disease." This conclusion is even more definite when the individual has a particular vulnerability, such as being immunocompromised due to chemotherapy.[93] In the COVID context, masks used as inhalation protection, like protecting the wearer from breathing in contaminated air, would be medical care.

The Internal Revenue Service (IRS) issued guidance at the beginning of 2021, stating that expenses for "personal protective equipment, such as masks, hand sanitizer and sanitizing wipes" are medical care under Code section 213(d) when used "for the primary purpose of preventing the spread of" COVID.[94] The IRS did not provide any analysis

91. I.R.C. § 213(a).

92. I.R.C. § 213(d)(1)(A). Section 213 defines other things as medical care, such as transportation of essential medical care and long-term care services; however, the PPE that this Article is suggesting should be covered would not fall under those other parts of the definition of medical care. *See generally* I.R.C. § 213.

93. There are special rules to help determine when cosmetic surgery is eligible "medical care," but because PPE is not used for cosmetic reasons it would not be subject to these special rules. I.R.C. § 213(d)(9).

94. I.R.S. Announcement 2021-7, News Release IR-2021-66 (Mar. 26, 2021) ("This announcement notifies taxpayers that amounts paid for personal protective

to support this conclusion. This guidance buttresses the conclusion that expenses incurred for personal protective equipment that is intended to protect the wearer are medical care. The guidance goes further by focusing generally on preventing the spread of a disease, not just preventing the contraction of a disease. This means that expenses incurred to protect the population generally are also medical care; for example, a mask worn as source control rather than inhalation protection.

One can imagine a variety of factors that the IRS could use in the future to limit guidance. At the time of the announcement, COVID was officially declared a pandemic and a public health emergency by the United States and the World Health Organization (WHO); in addition, the U.S. Department of Health and Human Services (HHS) issued guidance and mandates regarding the universal or widespread use of personal protective equipment to combat COVID.[95] While the COVID pandemic continues, both the WHO and HHS have lifted the public health emergency designations.[96] However, it is important to note that the IRS guidance is not conditional on, or tied to, whether COVID is a pandemic or a public health emergency. Thus, it should continue to be a valid support for treating expenses used to prevent the spread of COVID as medical care.

The IRS guidance is limited to the COVID context. It is unclear whether personal protective equipment used to prevent the spread of other illnesses would also be considered medical care under Code section 213(d). For example, a face mask can prevent not only the spread of COVID but also of influenza and RSV.[97] Ostensibly, the intent of the user matters because the IRS said the "primary purpose" must be the prevention of the spread of COVID.[98] This seems impossible to police.

---

equipment, such as masks, hand sanitizer and sanitizing wipes, for the primary purpose of preventing the spread of the Coronavirus Disease 2019 (COVID-19 PPE) are treated as amounts paid for medical care under § 213(d) of the Internal Revenue Code . . . .").

95. *Coronavirus Disease (COVID-19) Pandemic*, WORLD HEALTH ORGANIZATION [WHO], https://www.who.int/europe/emergencies/situations/covid-19 [https://perma.cc/6FBJ-HYGE] (last visited June 5, 2023) (providing the WHO declared COVID to be a pandemic on March 11, 2020, and has not lifted that designation; the WHO declared COVID to a public health emergency of international concern on January 30, 2020, and lifted that designation on May 5, 2023); *End of the Federal COVID-19 Public Health Emergency (PHE) Declaration*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 5, 2023), https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html [https://perma.cc/J49Z-82WQ] (noting that the federal COVID-19 public health emergency ended on May 11, 2023).

96. *End of the Federal COVID-19 Public Health Emergency (PHE) Declaration*, *supra* note 95.

97. Jane Dee, *From Flu to RSV, Masks Offer Everyday Protection from Respiratory* Illnesses, YALE SCH. OF PUB. HEALTH (Dec. 15, 2022), https://ysph.yale.edu/news-article/from-the-flu-to-rsv-masks-offer-everyday-protection-from-respiratory-illnesses/ [https://perma.cc/GK48-UQ32].

98. I.R.S. Announcement 2021-7, News Release IR-2021-66 (Mar. 26, 2021).

The Author highly doubts that the IRS would enforce such a restriction. Thus, the guidance is helpful for illnesses that are similar to COVID.

Personal protective equipment that might be useful against other contagious illnesses might not be useful against COVID, such as condoms used to prevent the spread of HIV or wound coverings to prevent the spread of impetigo. Condoms and wound coverings are effective at preventing the spread of these diseases but are not effective for preventing the spread of COVID.[99] The IRS guidance does not provide direct support for treating non-COVID expenses as medical care, because the IRS guidance was limited to personal protective equipment in the COVID context. However, the reasoning for extending this tax treatment to other contagious diseases is sound. The conclusion that personal protective equipment is medical care when used to prevent the spread of contagious disease should be generalizable to other diseases with a high risk of community spread. This conclusion is less certain but still possible for less contagious diseases with less risk of community spread.

To fully implement this Article's mandate, Congress should amend Code Section 213(d) or the IRS should issue guidance to clarify that "medical care includes amounts paid for personal protective equipment whose primary purpose is either to prevent the user from contacting an infectious disease or to prevent the spread of a contagious disease." Current law and guidance support this result, but a clear statement in the statute or administrative guidance would be helpful.

B. The Federal Income Tax Code: Tax Deduction

Individuals are allowed to deduct medical expenses against their income when calculating their federal income tax liability.[100] However, the medical expenses must meet the definition of medical care, and the deduction is subject to numerous limitations, narrowing its usefulness. Further, while Code Section 213 allows taxpayers to deduct eligible medical expenses from their income when computing their federal income tax liability, a taxpayer may not take a Code Section 213(d) medical expense deduction for any expenses that are "compensated for by insurance or otherwise."[101] Thus, a person cannot have a service paid for through insurance or be reimbursed for a service by a flexible

99. *Condom Fact Sheet*, U.S. AGENCY FOR INT'L DEV. (April 2015), https://www.usaid.gov/sites/default/files/2022-05/condomfactsheet.pdf [https://perma.cc/2BKD-9N36]; *see 10 Tips to Prevent Spreading Impetigo, and Avoid Getting It Again*, AM. ACAD. DERMATOLOGY ASS'N, https://www.aad.org/public/diseases/a-z/impetigo-self-care [https://perma.cc/9QUK-Q7J8] (explaining that wound coverings can prevent the spread of other diseases like Impetigo).

100. I.R.C. § 213(a).

101. *Id.*

spending account of health savings account and also take a tax deduction. This prevents double dipping.

Although an individual is permitted a deduction against income for qualifying medical expenses, the deduction is an itemized deduction.[102] When filing a federal income tax return, an individual must elect between taking the standard deduction or taking their eligible itemized deductions.[103] The standard deduction is adjusted for inflation every year.[104] For the 2022 tax year, the standard deduction for a person using the single filing status is $12,950 (higher for married couples filing joint returns, heads of household, people over the age of sixty-five, and people who are blind).[105] The standard deduction is a set amount that may be taken without reference to any actual expenses incurred. This means that a person's itemized deductions, including their medical expense deduction, must exceed the standard deduction in order to be useful. Given the nature of other common itemized deductions (mortgage interest on a principal residence plus one other residence,[106] state and local taxes not in excess of $10,000,[107] and charitable contributions[108]), many people will not be in a position where taking an itemized deduction for their purchase of personal protective equipment will be advantageous. Even with the ability to deduct the purchase of personal protective equipment , most taxpayers will have itemized deductions that total less than the standard deduction.[109]

This limitation is further compounded by the rule that eligible medical expenses are deductible (if the individual elects to deduct them in lieu of taking the standard deduction) only to the extent that the total eligible medical expenses for that tax year exceeds 7.5% of the individual's adjusted gross income.[110] This operates as a floor or deductible.

---

102. Code Section 213(a) defines qualifying medical expenses as an eligible deduction against income. I.R.C. § 63(d) defines an itemized deduction as any deduction other than personal exemptions amounts under I.R.C. § 151, the deduction under I.R.C. § 199(a), and any deduction used to determine adjusted gross income. I.R.C. § 62(a) and this list do not include the I.R.C. § 213 medical expense deduction that makes the I.R.C. § 213 deduction an itemized deduction.
103. I.R.C. § 63(b).
104. I.R.C. § 63(c)(4).
105. Rev. Proc. 2021-45; I.R.C. § 63.
106. I.R.C. § 163(h)(3).
107. I.R.C. § 164.
108. I.R.C. § 170.
109. *How Many Taxpayers Itemize Under Current Law?* TAX FOUND. (Sept. 12, 2019), https://taxfoundation.org/standard-deduction-itemized-deductions-current-law-2019/ [https://perma.cc/6GTC-2E3L] (estimating that for tax year 2019, only 13.7% of all taxpayers will itemize their deductions and noting that most taxpayers who itemize are in the topmost income levels).
110. I.R.C. § 213(a). This percentage had been set at 10% in some prior tax years, but is now permanently set at 7.5%, at least until Congress changes it again. *Maximize Medical Expense Deductions*, INTUIT (Aug. 12, 2021), https://www.firmofthefuture.com/content/maximize-medical-expense-deductions-for-2021/ [https://perma.cc/

The taxpayer must absorb the expenses up to this floor before being allowed to deduct any expenses above the floor amount. For example, if a taxpayer has an adjusted gross income of $100,000, the taxpayer will not be able to deduct the first $7,500 of eligible medical expenses due to the 7.5% floor; only eligible expenses over $7,500 are deductible. If the taxpayer has $10,000 of eligible medical expense, they will have an itemized deduction of $2,500.

Medicine and drugs other than insulin usually must be prescribed to be tax deductible.[111] A drug is prescribed if it is a "drug or biological which requires a prescription of a physician for its use by an individual."[112] This restriction is not embedded in the definition of medical care under Code Section 213(d). It is a separate limitation in Code Section 213(b) that applies only to the deduction available under Code Section 213(a). The restriction on over-the-counter drugs, thus, does not automatically carry over to employer plans and other reimbursement arrangements, which borrows the definition of medical care from Code Section 213(d), as discussed below. Over-the-counter drugs currently are eligible for reimbursement in a variety of reimbursement arrangements due to changes made in the CARES Act.[113] These rules are not relevant for most personal protective equipment that is used to combat infectious diseases directly. Masks, gloves, gowns, goggles, face shields, condoms, wound coverings, disinfectant sprays and wipes, and hand sanitizer are not drugs or biologics that require a prescription. However, some drugs and biologics could be considered personal protective equipment in certain situations. For example, some people started taking vitamin D supplements to avoid or reduce the severity of COVID infections.[114] It seems reasonable that this expense would be medical care under Section 213(d) as an "amount[] paid . . . for the . . . prevention of disease."[115] However, because vitamin D supplements do not require a prescription, they would not be tax deductible. These distinctions in current law could be relevant in assessing the limits of what could reasonably be considered personal protective equipment under this Article's proposal.

MKS7-A6SC] (explaining how medical expense deductions have changed over time).

111. I.R.C. § 213(b).
112. I.R.C. § 213(d)(3).
113. Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3702 (striking language restricting reimbursement arrangements from covering over-the-counter drugs and replacing that language with language permitting those same arrangements to cover menstrual care products).
114. Arrigo F.G. Cicero, Federica Fogacci & Claudio Borghi, *Vitamin D Supplementation and COVID-19 Outcomes: Mounting Evidence and Fewer Doubts*, NUTRIENTS, 2022, at 1.
115. I.R.C. § 213(d).

C. Flexible Spending Accounts and Other Reimbursement Arrangements

Apart from core medical coverage that a person might have through an employer health plan, a governmental program like Medicaid or Medicare, or a private insurance policy including an Affordable Care Act (ACA) marketplace policy, individuals may have tax-favored health care reimbursement arrangements, either as a stand-alone arrangement or as a supplement to other coverage. In these reimbursement arrangements, money is set aside in a separate account to help an individual pay for medical expenses that are not covered in another plan.[116] When these plans meet the qualification rules under the federal tax code, contributions to the plans are tax favored, as are disbursements from the plans, while contributions and qualified withdrawals are not subject to federal tax. Some of these arrangements may be offered only by employers, while individual taxpayers may establish others. Depending on the arrangement, an individual can make contributions directly or through payroll deductions. Alternatively, an employer can make contributions on behalf of the employee. Each of the arrangements discussed below are different in important ways. This Article does not seek to discuss those differences exhaustively. However, a brief overview of these arrangements and how they work is helpful in understanding how personal protective equipment for infectious diseases might be covered.

As discussed above, current law and guidance directly support the conclusion that personal protective equipment to prevent infection of the user with an infectious disease is a Code Section 213(d) expense, and personal protective equipment used to prevent the spread of COVID is a Code Section 213(d) expense. This Article argues that current guidance can be extended by analogy and support the conclusion that personal protective equipment used to prevent the spread of other contagious illnesses are also Code Section 213(d) expenses. Because these reimbursement arrangements are all tied to Code Section 213(d), these arrangements are allowed to, but not required to, cover personal protective equipment for infectious disease. This Article's proposed clarification of Code Section 213(d) would make this conclusion even clearer, but in the Author's view, it is not necessary for this conclusion. Fully implementing a mandate would require a relatively simple statutory change to require tax-favored reimbursement arrangements to cover "amounts paid for personal protective equipment whose primary purpose is either to prevent the user from contracting an infectious disease or to prevent the spread of a contagious disease." This is the same

116. *Using a Flexible Spending Account (FSA)*, HEALTHCARE.GOV, https://www.healthcare.gov/have-job-based-coverage/flexible-spending-accounts/ [https://perma.cc/4QWY-GJXW] (last visited Aug. 7, 2023).

change proposed for Code Section 213(d) definition of medical care but in a mandate form. Because many of these reimbursement arrangements are already written to allow the broadest coverage possible, they would comply with the proposed mandate.

A common employer arrangement is a flexible spending account (FSA). An employee with an FSA can use the FSA to pay for Code Section 213(d) medical care expenses that otherwise would have to be paid for by the employee out of pocket. An FSA can be used to pay for an employee's deductible, coinsurance, or copayments under the core medical plan. In addition, an FSA can be used to pay for goods and services not covered under the core health coverage as long as those goods and services meet the definition of medical care in Code Section 213(d). For example, an FSA might be used to purchase an arm splint or cold medicine. This use of FSAs is so widespread that national chain pharmacies print receipts that indicate which items are FSA eligible. While an employer may restrict the expenses eligible under its FSA, plans commonly reimburse for any Code Section 213(d) expense. An FSA may only be offered by an employer; an individual cannot established one.[117] When an employer contributes to an FSA, it is not considered taxable income to the employee.[118] If the employer has established a qualifying plan, an employee may make a contribution to an FSA through a Code Section 125 cafeteria plan payroll deduction, and that employee's contribution will be excluded from the employee's taxable income.[119] Thus, a reimbursement from a FSA is pre-taxable income. A reimbursement from an FSA that was funded by an employee using pre-tax dollars is the same, tax-wise, as the individual taking the expense as an itemized deduction, setting aside limitations like the 7.5% floor on the Code Section 213 expense deduction.

A Health Reimbursement Arrangement (HRA) is a reimbursement agreement that an employer must sponsor and that must be funded exclusively by an employer.[120] Employees are not allowed to contribute funds to an HRA.[121] Self-employed individuals generally are not

117. This is in part because FSAs are not explicitly authorized by the Code, unlike some other types of reimbursement arrangements. The IRS first discussed the tax-favored status of FSAs in an announcement, followed by proposed regulations, finding that a properly structured FSA qualifies under Section 105, which gives tax-favored status to employer-sponsored health plans. IRS News Release 94-22 (Feb. 1984); *see also* 49 Fed. Reg. 19,321 (1984) (demonstrating that under an FSA, an employee's account balance is forfeited at the end of each plan year to the extent it was not used during the plan year). This "use it or lose it" rule created enough risk that the IRS found that it functioned similarly to an employer health plan for purposes of Section 105.

118. I.R.C. § 105.

119. I.R.C. § 125.

120. Ryan Rosso, CONG. RSCH. SERV., R46782, A COMPARISON OF TAX-ADVANTAGED ACCOUNTS FOR HEALTH CARE EXPENSES 7–8 (May 3, 2021).

121. *Id.*

eligible to establish an HRA for themselves.[122] There are a few different varieties of HRAs that can be established, depending on the individuals that will benefit and the type of health plan available to those individuals.[123] Most HRAs must be integrated with health insurance coverage, either a plan offered by the employer or individual coverage purchased on an ACA marketplace unless the HRA is designed for retirees or intended to be an ACA excepted benefit.[124] As with an FSA, an HRA can reimburse Code Section 213 medical care expenses, although an employer may opt to limit the scope of reimbursable expenses, and there are some limits on reimbursing health insurance premiums depending on type of HRA.[125] Amounts unspent at the end of the plan year are allowed to carry over into the subsequent plan year, but the carry over amount may count against the annual contribution limit.[126]

Another common reimbursement arrangement is a Health Savings Account (HSA).[127] Created by Congress in 2003, an HSA is an individual account established by an individual who is covered only by a high deductible health plan. An HSA, much like an Individual Retirement Account (IRA), must be maintained by an eligible trustee or custodian, like a bank or credit union.[128] An individual can contribute to an HSA. Contributions are tax deductible in calculating adjusted gross income (i.e., above the line) and subject to some limitations, which means the deduction is available whether or not the taxpayer elects to itemize their deductions.[129] An employer may make contributions into an individual's account as well.[130] Such contributions are excludable from the employee's gross income for federal income tax purposes.[131] An employer may include an HSA as an option in the Code Section 125 cafeteria plan.[132] If the HSA is included in a Code Section 125 cafeteria plan, and if the employee makes a valid election to contribute to the HSA through payroll deduction, then the employee's payroll

122. I.R.S. Notice 2002-45, 2002-28 C.B. 93. However, if the business owner is also an employee of the business, then they may be able to establish an HRA, even if they are the only employee. For example, if the business is a C corporation and the sole shareholder is also the sole employee, they are eligible to use an HRA. It should be noted that most businesses are not set up in this manner due to other tax and business rules that make other forms more advantageous.
123. Ryan Rosso, CONG. RSCH. SERV., R47041, HEALTH REIMBURSEMENT ARRANGEMENTS (HRAS): OVERVIEW AND RELATED HISTORY 1-2 (Mar. 7, 2022).
124. *Id.* at 13–18.
125. *Id.*
126. *Id.* at 12.
127. I.R.C. § 223.
128. I.R.C. § 223(d)(1)(B).
129. I.R.C. § 223(a); I.R.C. § 62(a)(19).
130. INTERNAL REVENUE SERV., PUB. NO. 969, HEALTH SAVINGS ACCOUNTS AND OTHER TAX-FAVORED HEALTH PLANS, at 5 (Jan. 31, 2023).
131. *Id.* at 3, 8.
132. *Id.* at 3.

deduction contributions are excludable from their gross income for federal income tax purposes.[133] An HSA may reimburse the account beneficiary for medical care expenses as defined in Code Section 213(d).[134] Distributions for eligible expenses do not create taxable income for the beneficiary.[135]

Archer Medical Savings Accounts (Archer MSA or MSA) were available for self-employed individuals and employees of small companies prior to 2008.[136] Starting in 2008, eligibility for these accounts was restricted.[137] Individuals could not open new MSAs after the cutoff date, but any MSA that was in existence as of 2008 was grandfathered in.[138] Similarly, employers who offered an MSA to its employees as of 2008 generally could continue to maintain the MSA plan and could add new employees to those arrangements, but an employer could not establish a new MSA after the cutoff date.[139] MSAs operate very similarly to HSAs.

D. Employer Health Plan Coverage

The federal tax code plays a significant role in defining and influencing what services are covered by health insurance, both public and private. Normally, all amounts an employer pays to an employee or pays to someone else on behalf of an employee will result in taxable compensation income.[140] However, when an employer makes contributions to a qualifying health plan, typically in the form of premium payments for an insurance policy or contributions to a tax-favored reimbursement arrangement, Code Section 106 allow employees to exclude those contributions from their taxable income.[141] Relatedly, qualifying benefits that an employee receives under a qualifying health plan are not taxable income to them as a result of Code Section 105.[142] To illustrate, if an employer pays a portion or all of the premium for a qualifying health insurance policy for its employees, those premium payments are not included in the employee's taxable income for federal income tax purposes. Suppose an employee visits a doctor for a checkup or incurs some other eligible medical care expense. In that case, the employee

133. Rosso, *supra* note 120, at 10–11.
134. I.R.C. § 223(d)(2)(a).
135. I.R.C. § 223(f).
136. I.R.C. § 220.
137. I.R.C. § 220(i).
138. *Id.*
139. *Id.*
140. I.R.C. §§ 61(a)(1), 102(c).
141. I.R.C. § 106 ("Except as otherwise provided in this section, gross income of an employee does not include employer-provided coverage under an accident or health plan.").
142. I.R.C. § 105.

also has no taxable income when the qualifying health insurance policy pays for that doctor visit or reimburses the employee for that expense.

To be excludable from an employee's income, benefits paid, whether directly to the employee as a reimbursement or indirectly to medical providers on an employee's behalf), must be for "medical care" as defined in Code Section 213(d) and as discussed above.[143] While employers may provide benefits that fall outside this definition, such benefits would result in taxable income to the employee; thus, this is not common practice. The definition of medical care in Code Section 213(d) thus acts as a practical outer limit on the benefits employers are willing to offer in their health insurance programs.

Despite inclusion in the tax code's definition of "medical care," employer health plans typically do not cover most over-the-counter medical supplies, like personal protective equipment. Medical plans offered by employers and medical insurance policies offered by insurance companies typically restrict coverage to "medically necessary" goods or services. For example, the Author's university-sponsored medical insurance, administered by Blue Cross-Blue Shield, defines "medically necessary" care as:

> [A]ppropriate or necessary services as determined by a Provider/Practitioner in consultation with [Blue Cross-Blue Shield]. These services are provided to a participant for any Covered condition requiring . . . the diagnosis or direct care and treatment of an illness, injury, or medical condition, and are not services provided only as a convenience.[144]

Notice that the medical plan excludes prevention, whereas the tax code definition of medical care includes it. Personal protective equipment used prophylactically to prevent infection would qualify as preventive care.

This does not mean that private health insurance does not cover preventive care. The Affordable Care Act (ACA) requires almost all health plans to cover certain preventive care without any cost sharing; many plans covered preventive care even before the ACA mandate although cost sharing was common, and earlier plans typically did not cover preventive care.[145] The ACA does not provide an exact list of preventive care that must be covered but rather requires coverage of things recommended by expert organizations affiliated with the U.S.

---

143. I.R.C. § 105(b).

144. UNIV. OF N.M., UNIVERSITY OF NEW MEXICO LOBOHEALTH MEDICAL PLAN PARTICIPANT BENEFIT BOOKLET, EFFECTIVE JULY 1, 2021-JUNE 30, 2022 100 (July 1, 2021) (on file with the author).

145. 42 U.S.C. § 300gg–13; *A & B Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations// [https://perma.cc/Z6RW-9P45] (last visited Jan. 9, 2023).

Department of Health and Human Services (HHS).[146] For example, the ACA requires health plans to cover all "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force," a list which includes things like screening older men with a history of smoking for abdominal aortic aneurysm, providing breastfeeding support, and folic acid supplementation for individuals capable of pregnancy.[147] While it is possible that personal protective equipment used to prevent infection might fit within a mandatory preventive care category, that would not be the norm because historically preventive care that is included on these lists is clinical in nature. What is notable, however, is the trend toward including preventive services in medical plans. Even before the ACA mandate, many health plans recognized that covering preventive care results in lower costs overall.[148]

Private health plans also typically contain a host of exclusions that commonly preclude coverage of personal protective equipment used prophylactically to prevent infection. For example, the Author's health plan excludes "Common Disposable Medical Supplies that can be purchased over-the-counter such as but not limited to bandages, band aids, gauze (e.g. 4 by 4's), and Ace bandages, except when provided in a Hospital or Provider/Practitioner's office or by a home health professional."[149] It also states that "Nonprescription and Over-the-Counter Drugs are excluded," that "Protective Clothing or Devices are not covered under this Plan," and "Vitamins, dietary/nutritional supplements, special foods, formulas, or diets are not covered under this Plan."[150]

Currently, health plans may cover personal protective equipment as discussed in this Article, but it is not required. Thus, Congress will need to enact statutory changes for a mandate to be fully implemented. Those changes could be modeled on the ACA's mandate for preventive care. The statute should mandate that tax-favored employer health plan cover "amounts paid for personal protective equipment whose

146. 42 U.S.C. § 300gg–13. A recent federal district court case found that the ACA unconstitutionally delegated decision-making authority for mandated preventive care to individuals not appointed in accordance with the requirements of the U.S. Constitution. Braidwood Mgmt. v. Becerra, No. 4:20-cv-00283-O, Memorandum Op. & Ord. (N.D. of Tex. Sept. 7, 2022). Litigation is ongoing and the court has asked for additional briefing before deciding on an appropriate remedy. Laurie Sobel et al., *Explaining Litigation Challenging the ACA's Preventive Services Requirements: Braidwood Management Inc. v. Becerra*, KFF (May 15, 2023), https://www.kff.org/womens-health-policy/issue-brief/explaining-litigation-challenging-the-acas-preventive-services-requirements-braidwood-management-inc-v-becerra/ [https://perma.cc/26KT-6WEH].

147. 42 U.S.C. § 300gg–13; *A & B Recommendations*, *supra* note 145.

148. Michael V. Maciosek et al., *Greater Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost*, 29 HEALTH AFFS. 1656, 1656–60 (Sept. 2010).

149. UNIV. OF N.M., *supra* note 144, at 68.

150. *Id.* at 74.

primary purpose is either to prevent the user from contracting an infectious disease or to prevent the spread of a contagious disease."

E. Medicaid and CHIP

After employer health plans, the second most significant source of health coverage is the Medicaid program. Medicaid is a federal program that provides federal funding to states that operate an approved health care program targeted primarily at lower-income individuals and people with disabilities or other special medical needs.[151] Medicaid programs are funded with state and federal dollars, with the federal government matching state funds.[152] With some exceptions, the federal match is a minimum of 50% and a maximum of 83% and varies depending on the state's per capita income, with states whose residents are poorer receiving a higher match.[153]

Every state has a Medicaid program, even though participating in Medicaid is voluntary. States are required to offer a program that meets broad minimum federal guidelines for eligibility and plan design.[154] There is room for state flexibility; even within the broad federal guidelines of permissible design, there is a fair degree of difference from state to state.[155] For example, states must cover certain mandatory benefits, such as hospital services and physician services; however, states maintain latitude with respect to offering optional benefits, like prescription drugs, physical therapy, and dental care.[156]

States have broad latitude when deciding the scope of services that will be covered, such as the duration of medical care and the reimbursement rate for the providers. States also have latitude in defining the delivery of services, such as whether to use fee for service reimbursement or employ managed care techniques such as networks of providers and risk shifting to providers.[157] In addition to the flexibility afforded by the basic Medicaid program, states can apply for a waiver

151. *See Eligibility*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/eligibility/index.html [https://perma.cc/5KM3-CBL3] (last visited Jan. 9, 2023).
152. Alison Mitchell, CONG. RSCH. SERV., R43847, MEDICAID'S FEDERAL MEDICAL ASSISTANCE PERCENTAGE (FMAP) 2 (July 29, 2020).
153. *See id.* at 2.
154. *Eligibility*, *supra* note 151; Samantha Artiga et al., *Current Flexibility in Medicaid: An Overview of Federal Standards and State Options*, KFF (Jan. 31, 2017), https://www.kff.org/report-section/current-flexibility-in-medicaid-issue-brief/ [https://perma.cc/4BVA-JCSL].
155. *See supra* note 153.
156. *Mandatory & Optional Medicaid Benefits*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/benefits/list-of-benefits/index.html [https://perma.cc/RX9G-3XW9] (last visited Jan. 9, 2023).
157. Matt Broaddus, *Medicaid at 50: For States, Flexible Rules and Reliable Funding*, CTR. ON BUDGET & POL'Y PRIORITIES (July 6, 2015, 5:45 PM), https://www.cbpp.org/blog/medicaid-at-50-for-states-flexible-rules-and-reliable-funding [https://perma.cc/S6D6-6P2C].

of certain aspects of the Medicaid program under Section 1115 of the Social Security Act in order to adopt changes that are "likely to assist in promoting the objectives of" Medicaid.[158]

Medicaid eligibility is complex, and while the details are beyond the scope of this Article, it is helpful to understand that different populations are eligible for Medicaid coverage. [159] The Medicaid statute requires states to cover certain categories of individuals, referred to as "categorically needy."[160] These categories include very low-income families, qualified pregnant women and children, individuals receiving Supplemental Security Income (SSI) (a federal needs-based cash assistance program), and people who are disabled.[161] In addition to the categorically needy, who states are required to cover, states have the option to cover additional populations, such as medically fragile individuals (individuals receiving home and community-based services), children in foster care, and qualifying pregnant women, children, and caregivers with slightly more income than is allowed under the categorically needy definitions.[162] Further, the ACA provides incentives for the states to expand eligibility for Medicaid coverage to include all adults under age sixty-five with incomes up to 138% of the poverty line.[163] Children with income 138% of the poverty line or less were already eligible for Medicaid prior to the passage of the ACA.[164]

Federal Medicaid law requires a broad range of preventive care be covered for children under the age of twenty-one and requires coverage of family planning services. [165] Preventive care for most non-expansion

158. 42 U.S.C. § 1315(a). Waivers also are available for demonstration programs that promote the objectives of specified programs other than Medicaid, such as old age assistance, aid to the blind, aid to persons with permanent and total disability, SSI or supplemental security program, TANF (formerly known as welfare), or child support enforcement programs.

159. For details of eligibility rules in all fifty states, see *Medicaid State Fact Sheets*, KFF (Oct. 3, 2022), https://www.kff.org/interactive/medicaid-state-fact-sheets/ [https://perma.cc/J24W-TJMB].

160. *Supra* note 151.

161. *Id.*

162. *Id.*

163. 42 U.S.C. § 1396a(10)(A)(i)(VIII). The federal poverty figures are published by the Department of Health and Human Services in the Federal Register at the start of every year. For 2021, the poverty line for a single individual not living in Alaska or Hawaii is $12,880. Each additional family member adds $4,540 to the poverty line. Annual Update of HHS Poverty Guidelines, 86 Fed. Reg. 7732 (Feb. 1, 2021). Thus, for 2021, 138% of the federal poverty line for a single person is $17,774. The poverty line is higher in Alaska and Hawaii. *Id.* While the statute pegs eligibility for the Medicaid expansion at 133% of poverty, the statute allows up to 5% of income to be disregarded; thus, the actual income limit is 138% of poverty. 42 U.S.C. § 1396a(7)(B)(i).

164. *Medicaid Expansion & What It Means for You*, HEALTHCARE.GOV, https://www.healthcare.gov/what-if-my-state-is-not-expanding-medicaid/ [https://perma.cc/29VJ-8MUV] (last visited Jan. 9, 2023).

165. 42 U.S.C. § 1396d(a)(4)(B); 42 U.S.C. § 1396d(r)(5).

adults continues to be optional for states, although there are financial incentives in place for states that expand preventive care to non-expansion adults.[166] Most states have elected to cover preventive care for non-expansion adults, and there is a wide degree of variety in what is covered and under what terms.[167] Like employer-sponsored and private plans, however, it is not the norm for personal protective equipment used to prevent infection to be covered, although it is possible that personal protective equipment might fit within a preventive care category in certain situations. However, the trend toward including more preventive services as "covered services" is notable.

Like employer-sponsored health plans, Medicaid does not provide general coverage for over-the-counter medical supplies. Some medical supplies, including personal protective equipment, are covered if provided as part of approved home health care services.[168] However, Medicaid generally does not mandate or permit such coverage.

Implementing this Article's mandate in Medicaid would require an amendment to the federal statute. Depending on the scope of the mandate discussed further below, Congress could amend the federal statute to make the coverage a mandatory feature of state Medicaid programs. Alternatively, this coverage could be implemented as a permissible state variation. Finally, even if the federal statute is not amended, a state wishing to provide this coverage to Medicaid beneficiaries could request a Section 1115 waiver by demonstrating that deviation in coverage is "likely to assist in promoting the objectives of" Medicaid."[169]

F. Medicare

Medicare is a health insurance program run by the federal government without the involvement of the states. Medicare covers older individuals (age sixty-five or over) with a sufficient record of qualifying work (currently forty quarters or ten years), as well as certain disabled individuals, and individuals with end-stage renal disease or ALS.[170] Traditional Medicare consists of Part A (covering inpatient

166. Naomi Seiler et al., *Coverage of Clinical Preventive Services Under the Affordable Care Act: From Law to Access*, 129 PUBLIC HEALTH REPS. 526, 529 (2014).

167. OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS., *Access to Preventive Services without Cost-sharing: Evidence from the Affordable Care Act* 6 (Jan. 11, 2022).

168. *COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies*, CTRS. FOR MEDICARE & MEDICAID SERVICE 91–92 (Jan. 26, 2021), https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf [https://perma.cc/5HFH-L8UZ].

169. 42 U.S.C. § 1315(a).

170. *Who is Eligible for Medicare?*, DEP'T HEALTH AND HUMAN SERVS., https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html [https://perma.cc/4N72-FJT7] (last visited Jan. 10, 2023).

care, hospice, and home health care) and Part B (covering outpatient care).[171] In traditional Medicare, there are no networks; patients obtain services from any facility or provider that accepts Medicare, and Medicare reimburses a portion of the bill on a fee-for-service basis.[172] Part D of Medicare covers prescription drugs, and is commonly paired with Parts A and B.[173] Traditional Medicare has relatively high cost sharing in the form of deductibles and coinsurance and also has no limit on the amount an individual must pay out of pocket.[174] Thus, it is common for people to also buy supplemental coverage; sometimes employers provide supplemental coverage to actively working Medicare-eligible employees or to retirees, Medicaid and Tricare (for military retirees) can supplement Medicare, or individual can buy private policies known as Medigap insurance.[175] Part C of Medicare, also known as Medicare Advantage, is an alternative to traditional Medicare that replaces Parts A and B and typically also replaces Part D, sometimes providing extra benefits like vision, hearing or dental services.[176] Part C plans are approved by the federal government but are private insurance products; they typically have network restrictions and preapproval requirements, commonly have lower out-of-pocket costs, and have an annual out-of-pocket maximum.[177] Medigap policies cannot be paired with a Part C plan, although other supplemental coverage may coordinate their benefits with a Part C Medicare plan.[178]

Like with employer-sponsored plans, private insurance, and Medicaid, Medicare does not cover the full spectrum of what would be considered "medical care" under the federal tax code. Traditional Medicare does cover a broad array of preventive care services, such as vaccines and screenings, but those services are largely clinical.[179] This means that personal protective equipment used prophylactically to prevent infection is not covered as "preventive care" in traditional Medicare. Traditional Medicare does not cover over-the-counter medical supplies (such as masks, gloves, and bandages), although it does cover some over-the-counter drugs, medical supplies used as part of home health care services, and medical supplies that meet the definition of durable

171. *Medicare & You*, DEP'T HEALTH AND HUMAN SERVS. 9–10 (2023), https://www.medicare.gov/forms-help-resources/medicare-you-handbook/download-medicare-you-in-different-formats [https://perma.cc/CCJ9-R5WL].
172. *Id.* at 11.
173. *Id.* at 9–10.
174. *Id.* at 11–12.
175. *Id.* at 10.
176. *Id.*
177. *Id.* at 10–12.
178. *Id.* at 11.
179. *Id.* at 29–56 (providing a list of covered services, with preventive care marked by an apple).

medical equipment.[180] Most personal protective equipment does not fit into these categories, however.

Medicare Part C plans have the flexibility to cover personal protective equipment as an extra service, and many Part C plans include a wellness allowance that would include personal protective equipment .[181] One study found that in 2021 nearly 80% of all Medical Advantage plans offered an allowance for the purchase of over-the-counter products as a supplemental benefit.[182] The details of the over-the-counter plans vary: plans differ with regards to what is covered, how the products can be obtained, and what the overall allowance is. However, the Florida Health Plan Blue Cross Blue Shield Medicare OTC program for 2021 has a catalog of allowable items, and "procedural face masks with ear loops," "hand sanitizer," and "nitrile exam gloves" are included while disinfecting wipes are not.[183] The Wellcare 2022 Medical Advantage program covers "Surgical Face Masks," "Hand Sanitizer," and "Antibacterial Resealable Wipes," but not gloves.[184] Neither plan covers respirators, like N95 or KN95 masks that provide superior protection against COVID.

To implement a mandate such as this into Medicare would require changes to federal statutes and regulations. The mandate would most sensibly be included with Part B coverage, which would automatically make the mandate part of what Part C plans are required to cover.

IV. DESIGNING A MANDATE

Part IV analyzes why PPE should be covered at zero cost by health coverage plans and explores the contours of such a mandate.

A. Why a Mandate Is Desirable: Policy

Health insurance should not cover everything that promotes health. Any such policy would make the cost of health insurance would

180. *Id.* at 40, 62.

181. *Medicare Advantage Plans Cover All Medicare Services*, MEDICARE.GOV, https://www.medicare.gov/what-medicare-covers/what-medicare-health-plans-cover/medicare-advantage-plans-cover-all-medicare-services [https://perma.cc/TJV6-UMTR] (last visited Jan. 12, 2023).

182. *Using the Medicare Advantage Over-the-Counter (OTC) Medicines Program as a Consumer Engagement Tool*, CONSUMER HEALTHCARE PRODUCTS ASS'N (2021), https://www.chpa.org/about-consumer-healthcare/research-data/research-reports/using-medicare-advantage-over-counter-otc-consumer-engagement [https://perma.cc/47EG-KEGL].

183. *Over-the-Counter (OTC) Benefits*, FHCP MEDICARE 9 (2022), https://www.fhcpmedicare.com/documents/medicare/2022/OTCCatalog_470_471.pdf [https://perma.cc/VL2T-5DZJ].

184. *Over-the-Counter (OTC) Catalog: Medicare Advantage Plan 2022*, WELLCARE 16, 26 (2021), https://croweandassociates.com/wp-content/uploads/2021/12/Wellcare-OTC-catalog-2022.pdf [https://perma.cc/C86B-YA7J].

be prohibitive, placing insurance out of reach for the average person. The literature on social determinants of health has convincingly demonstrated how a variety of social factors, like access to quality housing and food, impacts our health.[185] Nevertheless, health insurance does not cover rent, a mortgage, or a grocery bill. Health insurance typically focuses on costs to diagnose and treat injury and illness through clinical interventions.

Health insurance sometimes covers goods and services that are not designed to diagnose or treat an injury or illness, or at least not clearly so. Modern health insurance has extended coverage to conditions like pregnancy that affect health but cannot be clearly classified as an injury or illness.[186] Modern health insurance also has extended coverage to include certain preventive care, which in many cases is designed to avoid injury or illness rather than diagnose or treat it or to detect illness or injury early when treatment is often less extensive or invasive and more effective. These coverage expansions have often occurred as a result of legal shifts.

For example, pregnancy does not fit neatly into the definition of illness or injury. Illness or injury typically is understood as a deviation from the normal function of the human body, with treatment expected to return the body to normal function.[187] Pregnancy without

185. *See, e.g.*, Scott Burris, *From Health Care Law to the Social Determinants of Health: A Public Health Law Research Perspective*, 159 U. PA. L. REV. 1649, 1649 (2011) ("Research over the past three decades has demonstrated that population health is shaped powerfully by 'the contexts in which people live, learn, work, and play' - also called 'social determinants of health' or 'fundamental social causes of disease'"); Jessica Mantel, *Tackling The Social Determinants Of Health: A Central Role For Providers*, 33 GA. ST. U.L. REV. 217, 221–22 (2017) ("Together these factors, the so-called social determinants of health, account for 60% of the risk of premature death due to chronic disease and other health conditions. So although . . . improving the delivery of health care is an important goal, health experts have concluded that ameliorating the social, environmental, and behavioral conditions that contribute to chronic disease holds even greater promise for enhancing the population's health and constraining health care spending.").

186. *What Services Do Plans Have to Cover for Pregnancy?*, KFF, https://www.kff.org/faqs/faqs-health-insurance-marketplace-and-the-aca/what-services-do-plans-have-to-cover-for-pregnant-women/ [https://perma.cc/647K-Z9RN] (last visited Aug. 18, 2023).

187. *See* Katskee v. Blue Cross Blue Shield of Neb., 245 Neb. 808, 816, 515 N.W.2d 645, 651 (1994) (providing that in the context of determining whether a health insurance policy covers a total abdominal hysterectomy and bilateral salpingo-oophorectomy to treat the genetic condition known as breast-ovarian carcinoma syndrome the "plain and ordinary meaning of the terms 'bodily disorder' and 'disease,' as they are used in the policy to define illness, encompasses any abnormal condition of the body or its components of such a degree that in its natural progression would be expected to be problematic; a deviation from the healthy or normal state affecting the functions or tissues of the body; an inherent defect of the body; or a morbid physical or mental state which deviates from or interrupts the normal structure or function of any part, organ, or system of the body and which is manifested by a characteristic set of symptoms and signs.").

complications, on the other hand, is a normal function of the human body, although it clearly has an impact on the mother's health. It was common for health insurance policies to exclude pregnancy altogether or to cover pregnancy only through the purchase of expensive riders that had waiting periods.[188] Congress eventually stepped in to require pregnancy coverage. Congress passed the Pregnancy Discrimination Act in 1978, which prohibited health insurance plans from treating pregnancy-related conditions less favorably than other medical conditions.[189] In practical terms, this meant that pregnancy had to be a covered service in employer-sponsored health plans.[190] Thirty-two years later, the Affordable Care Act directly mandated coverage of pregnancy not only in employer-sponsored health plans but also in individual policies.[191]

Similarly, modern health insurance now covers preventive care designed to detect illness early (such as mammograms), prevent illness from occurring, or lessen its severity (such as vaccinations). Some expansions to include preventive care came from the health insurance companies themselves to lower their overall costs. It is natural to assume that prevention is good for a health insurer's bottom line, although the evidence is highly mixed about whether this is correct.[192]

188. Louise Norris, *How Obamacare Changed Maternity Coverage*, HEALTHINSURANCE.ORG, https://www.healthinsurance.org/obamacare/how-obam acare-changed-maternity-coverage/ [https://perma.cc/A8EM-BY3D] (last visited Jan. 13, 2023).

189. Pregnancy Discrimination Act of 1978, Pub. L. No. 95-555, 92 Stat. 2076 (Oct. 31, 1978) (amending Title VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000e et seq., to prohibit sex discrimination on the basis of pregnancy, childbirth, or related medical conditions).

190. *See, e.g.*, Newport News Shipbuilding & Dry Dock Co. v. EEOC, 462 U.S. 669, 685 (1983) (noting that the employer amended its health plan to cover pregnancy for female employees in response to the passage of the Pregnancy Discrimination Act and finding that the employer's attempt to exclude pregnancy for female dependents, i.e., the spouses of male employees, constituted prohibited sex discrimination because male dependents enjoyed complete coverage).

191. Norris, *supra* note 188.

192. Kenneth R. Pelletier, *A Review and Analysis of the Health and Cost-Effective Outcome Studies of Comprehensive Health Promotion and Disease Prevention Programs at the Worksite: 1993-1995 Update*, 10 AM. J. HEALTH PROMOTION 380 (1996) (surveying multiple studies that all found a positive health and cost impact of workplace health promotion programs); Kristin Leutwyler, *The Cost of Prevention*, SCI. AM. 124 (Apr. 1995) (noting that multiple studies have found that the cost of clinical disease prevention often outstrips the cost of disease treatment); Allison K. Hoffman, *Three Models Of Health Insurance: The Conceptual Pluralism Of The Patient Protection And Affordable Care Act*, 159 U. PA. L. REV. 1873, 1893–94 (2011) (noting that "[e]vidence suggests that that much prevention and early treatment of disease is not cost saving - at either the individual or the system level" and discussing the various reasons why this would be so). The correlation between cost and quality of health care is rarely as linear as we would expect or hope. Widespread screening may avoid disease but cost more than targeted treatment and the avoidance of disease and the extension of life may simply shift lifetime medical costs to an individual's later years. Cost is rarely a helpful metric standing alone;

More significantly, covering preventive care improves overall health outcomes. It also probably helps that covering preventive care can help employers retain employees and can help insurers attract customers.

While there is a wide variety, states have been active in enacting benefit mandates, including mandates to cover preventive care services.[193] States have the authority to mandate coverage for insurance policies issued in their state; as such, mandates have typically impacted individual health insurance policies and sometimes group policies sold to employers. States do not have the authority to regulate self-funded employer plans due to ERISA preemption, so state mandates are unable to reach all health plans that cover their residents.[194]

Congress passed several insurance mandates pre-ACA, such as mandating coverage of minimum hospital stays for newborns and mothers, requiring parity in annual and lifetime benefit limits for mental health care, and requiring coverage of reconstructive surgery following a mastectomy.[195] With the ACA, Congress made sweeping changes to health insurance. Under the ACA, all individual health insurance policies and small group health plans must cover a set of "essential health benefits."[196] While the details of what exactly is covered in each category varies from state to state, the essential health benefits that must be covered are (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.[197]

When Congress or state legislatures mandate coverage in health insurance, it can often be understood as a public health measure. Mandating coverage of pregnancy supports healthy infants, an important public health goal. Mandating preventive care promotes a healthy

---

it must always be evaluated in the context of the goals for incurring the cost. As Professor Hoffman notes, "Most practitioners agree, however, that preventive care is valuable even if not cost saving because it can increase quality of life or extend years of life . . . . Thus, even as some cost savings are possible, the primary justification for Health Promotion insurance is the value or cost-effectiveness of such interventions in improving health and quality of life." *Id.* at 1894–95.

193. Justin Giovannelli, Sabrina Corlette & Madeline Obrien, *The ACA's Preventive Services Benefit Is in Jeopardy: What Can States Do to Preserve Access?*, THE COMMONWEALTH FUND (Nov. 21, 2022), https://www.commonwealthfund.org/blog/2022/aca-preventive-services-benefit-jeopardy-what-can-states-do#2 [https://perma.cc/Q37A-APAA].

194. *Id.*

195. 42 U.S.C. § 201 note.

196. *Information on Essential Health Benefits (EHB) Benchmark Plans*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/cciio/resources/data-resources/ehb [https://perma.cc/4BRG-HBG4] (last visited Aug. 18, 2023).

197. Patient Protection and Affordable Care Act of 2010 § 1302, 42 U.S.C. § 157.

population. In other words, public health principles can and do inform health insurance design and health insurance legislative policy. This Article's proposal is strongly correlated to public health goals. Making personal protective equipment easily available to those most at risk of infectious diseases promotes at least two public health goals. First, to the extent that more vulnerable individuals are better protected against infection, disease spread and outbreaks should be lessened, and the number of severe infections should be lower. Thus, the proposal promotes one of the classic public health goals of controlling infectious diseases at a population level. Second, mandating special protections for the most vulnerable through health insurance may enable public health authorities to avoid or use more sparingly draconian infection control measures like lockdowns, which often come with high social and economic costs. In other words, a personal protective equipment mandate can be a core part of public health efforts to combat infectious diseases at a community level.

Personal protective equipment used by vulnerable individuals to boost their protection against infectious diseases is different from other consumable medical supplies used in connection with non-infectious injury or illness. A disposable syringe used by an individual to inject a drug that treats a disease is beneficial to the person with the disease but has no health benefit for the broader community.[198] An over-the-counter bandage used to cover a wound is beneficial to the individual with the wound because the bandage keeps the wound clean which prevents infection and promotes healing; the bandage is only marginally useful to the health of the broader community, possibly avoiding the spread of blood-borne pathogens that could be present in the wound.[199] A mask used by an immunocompromised person to reduce the risk of catching COVID-19 or influenza benefits the individual using the mask and the broader community because of the extent that mask use slows the spread of illness.[200] The difference between these examples is that the vaccine involves no infectious disease, the bandage involves an infectious disease that is not very contagious; the principal purpose for the bandage protects the individual from infection, and the mask

198. Disposable syringes are good example of an over-the-counter consumable medical supply that is covered by insurance in many cases. Diabetes supplies, such as disposable syringes used to inject insulin, are sometimes required to be covered by state law. *See, e.g.*, N.M. STAT. ANN. § 59A-22-41 (2023). While diabetes supplies are an optional Medicaid coverage, almost all states cover at least some diabetes supplies, and Medicare covers many diabetes supplies through Parts B and D. *Financial Help for Diabetes Care*, NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASES (June 2019), https://www.niddk.nih.gov/healthinformation/diabetes/financial-help-diabetes-care [https://perma.cc/F2F9-8PMS].

199. *See MRSA and the Workplace*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 13, 2023), https://www.cdc.gov/niosh/topics/mrsa/default.html [https://perma.cc/3LWX-7DFQ].

200. *See* Kristin L. Andrejko et al., *supra* note 87, at 13.

protects both the individual and the community from contagion. These differences are salient when creating public policy.

B. Scope of the Mandate

1. What is PPE?

A preliminary matter is to clarify what is considered personal protective equipment under this Article's proposal. The items that most people think of as personal protective equipment—masks, hand sanitizer, gloves—are Class I medical "devices" regulated by the FDA. A medical "device" is defined in the Federal Food, Drug, and Cosmetic Act as an:

> instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[201]

As discussed in the next section,[202] this definition has significant overlap with the definition of medical care in the Federal Income Tax Code. Class I medical devices are those that are considered low-risk—the manufacturing and quality control standards to which they are subject are sufficient to "provide reasonable assurance of the safety and effectiveness"[203] of the device or they otherwise do not "present a potential unreasonable risk of illness or injury."[204] Examples are bandages and enema kits. The personal protective equipment included in this Article's mandate are those items that are considered medical devices under this definition.

2. A Broad Mandate

The scope of the mandate could be very broad, targeted, or somewhere in between. A broad mandate would require a health benefit plan to cover "amounts paid for personal protective equipment whose primary purpose is either to prevent the user from contracting an

201. 21 U.S.C. § 321(h)(1).
202. *See infra* Part IV.B.2
203. 21 U.S.C. § 360c(a)(1)(A)(i).
204. 21 U.S.C. § 360c(a)(1)(A)(ii)(II).

infectious disease or to prevent the spread of a contagious disease" and would clarify the definition of medical care in Section 213(d) to include the same language. For example, masks used to block airborne transmission of pathogens like the viruses that cause COVID-19 or influenza would be covered; disinfectant wipes to sanitize surfaces to block surface transmission of a pathogen would be covered; condoms used to reduce the risk of sexually transmitted pathogens would be covered; mosquito nets to protect from Zika or West Nile virus would be covered.

There would be no limits on the diseases that qualify, providing the disease is infectious or contagious. There would be no gatekeeping function. If an individual feels the need to buy masks to protect against contagious illness, they could do so without pre-approval of the health plan or a health care professional. Normal fraud rules would apply.

This is the way the income tax deduction and most FSA accounts work. This approach would reduce the need to draw lines, making it more efficient to understand and administer. The principal downside of a broad mandate is cost, and high cost has ripple effects on health insurance affordability and access. A very broad mandate may also be politically unrealistic.

3. A More Targeted Mandate

An alternative to a broad mandate is a targeted mandate rooted in both public health principles and the traditional clinical focus of health insurance. Such a mandate would require coverage of amounts paid for personal protective equipment whose primary purpose is to prevent the user from contracting an infectious disease, provided that a qualified health care practitioner has identified the user as having a diagnosed illness or injury that makes the user have a heightened vulnerability to the infectious disease, and provided that the qualified health care practitioner has identified the particular personal protective equipment to be used.

Under this approach, the mandated coverage benefits the individual as well as the broader community of which the individual is a part. Providing the personal protective equipment that a person uses to protect themselves from a communicable disease helps that individual and benefits the broader community by reducing the spread of the communicable disease. This type of mandate also fits well with the traditional clinical focus of health insurance. While there are public health benefits to the coverage, the personal protective equipment is necessary because the individual has an individual condition that makes it necessary. The personal protective equipment is not only preventing a disease (like COVID-19) but also treating a disease (like cancer). Consider the Author's father-in-law, discussed in the introduction.[205] His

205. *See supra* Part I.

doctor recommended mask wearing for him as part of his cancer treatment. Staying healthy is critically important for his prognosis, and his chemotherapy treatment seriously weakens his immune system, making staying healthy much more challenging. Thus, the masks are made necessary by cancer, although they are intended to prevent other illnesses such as COVID-19, influenza, and RSV.

There are equity arguments in favor of such an approach as well. If an individual has a diagnosed injury or illness and needs a medical device to help manage that condition, then covering that medical device makes sense. Requiring the individual to pay out of pocket for the entire cost of the needed medical device is more likely to result in noncompliance with medical instructions.[206] Requiring patients to self-pay for such items also increases health inequities because lower-income individuals are more likely to forego using the medical device due to economic need. The resulting health inequities are likely to reinforce pre-existing racial and ethnic inequities because there is a high correlation between lower incomes and populations that fall outside non-dominant groups.[207] It also undercuts the value of health coverage as a tool for managing the financial risk of injury or illness.[208]

Requiring a healthcare practitioner to be involved provides several protections. It helps to prevent fraud and waste. An individual would not be able to log onto Amazon, click a box that they have an underlying condition, and obtain an unlimited supply of free masks (or disinfecting wipes) that may go unused or could be resold. It also helps to ensure that the use of the personal protective equipment is appropriate for the individual. For example, should an individual utilize a face mask? Should it be a particular type of face mask? Should gloves be used? Disinfecting wipes? A face shield? Condoms? The answer to these questions largely depends on the traits of the particular infectious disease or diseases being targeted (i.e., transmitted primarily through air, surface, or through another form) but also on the type of underlying health condition that makes the individual vulnerable. To illustrate, a person with a preexisting respiratory disorder (like asthma) might be especially vulnerable to infectious respiratory diseases like COVID-19 or influenza but non-respiratory infectious diseases (like viral or bacterial gastroenteritis) might not pose a greater risk to that person than it poses to the general population. The individual would need to talk with a health care practitioner about what personal protective equipment is appropriate, how to use it, and when. Healthcare practitioners have the skills to ensure that the individual

206. Alex Montero et al., *Americans' Challenges with Health Care Costs*, KFF (July 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/ [https://perma.cc/3FRG-92TA].

207. *See* Bettina M. Beech, et al., *Poverty, Racism, and the Public Health Crisis in America*, 9 FRONTIERS IN PUB. HEALTH 1, 2 (Sept. 6, 2021).

208. Hoffman, *supra* note 192.

has a condition that would benefit from the use of the personal protective equipment. They also can assess the relative risks of various communicable diseases. This personal protective equipment authorization could look like a prescription.

The CDC, or a similar organization, could determine whether a disease is infectious or not, could determine the contagiousness of the disease, and could determine the particular vulnerabilities associated with each qualifying infectious disease. However, because the question of what measures would be effective to protect an individual with an identified vulnerability from a variety of infectious diseases is a very particularized inquiry, it is not well suited to general guidance released by an organization like the CDC. Rather, a more personalized approach is desirable. A licensed healthcare provider whose scope of practice includes creating care plans for individuals with illness or injury could serve this gatekeeping function. This could be a physician but could also be a nurse or a pharmacist, depending on the state's health care licensing laws. A consultation could also occur through telehealth, depending on the state's laws. The prescribing provider would be able to determine the individual's needs and issue a prescription for personal protective equipment that would address the individual's needs. Various claims methods could be employed. Like the COVID-19 over-the-counter tests, the individual could submit a claim directly to their insurance provider for reimbursement, or personal protective equipment could be available behind a pharmacy's counter with the pharmacy submitting the claim to insurance.

4. A Narrower Mandate

While the Author strongly prefers the targeted mandate, it may be necessary to narrow the mandate further to control costs or make the proposal more politically viable. In this situation, the scope of the mandate could be further limited by targeting particular infectious diseases. Legislation could take the approach of naming particular targeted diseases, although the Author does not recommend this approach because the list will likely become outdated quickly as new diseases like COVID-19 arise and others become less of a threat. Legislation could target diseases based on their risk to the population at large. For example, the mandate could require that any disease classified by the CDC as an epidemic or an outbreak of an endemic disease would qualify for coverage. However, this approach depends on a reliable organization with the tools and skills to classify disease by contagiousness.

There may be diseases that are so contagious that the government would mandate coverage of protective gear for everyone. For example, to help combat the COVID-19 pandemic, the U.S. government mandated that health insurance cover up to eight over-the-counter tests

per covered person per month.[209] It may be desirable to target access to control costs and further avoid waste and hoarding problems. The mandate could target individuals with only particular vulnerabilities to infectious diseases. For example, with respect to COVID-19, individuals who are unable to receive a vaccine (i.e., due to allergy)[210] or for whom vaccines are less effective (i.e., individuals who are moderately or severely immunocompromised)[211] are at a heightened risk of infection; individuals with particular underlying health conditions (i.e., diabetes) are at a heightened risk of serious illness if they are infected.[212] This sort of limitation is fairly complex, requiring a scientific assessment of a wide array of vulnerabilities for a wide array of infectious diseases.

V. CONCLUSION

COVID-19, and the multitude of responses to it, upended almost every facet of life. No one was left untouched by the pandemic and the public health response to it. One of the lessons from the experience is the importance of a shared physical vulnerability. Our public policies should take into account the fact that many people are intensely physically vulnerable due to disability, disease or preexisting conditions—in a way that is not dissimilar to the vulnerability most of us experienced in the early days of the COVID-19 pandemic.

There is a continuing imperative to adopt public policies that will protect the public's overall health, both in the COVID-19 context and in the context of other contagious illnesses like influenza, RSV, HIV-AIDS, and more. Our public health strategies for combatting contagion can include private health insurance coverage. Giving the most

209. Katie Keith, *Insurers and Plans Must Cover At-Home Tests For COVID-19*, HEALTH AFFS. (Jan. 11, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220111.960247/ [https://perma.cc/NCY7-FG37].

210. *Information for Special Populations and the COVID-19 Vaccine*, YALE HEALTH (Sept. 16, 2022), https://yalehealth.yale.edu/yale-covid-19-vaccine-program/information-special-populations-and-covid-19-vaccine [https://perma.cc/P8ML-DGWK]. Severe allergic reactions to COVID vaccines are rare and most people can safely receive one of the COVID vaccines. *Id.* The vaccine was not authorized by the Food and Drug Administration (FDA) for use in children under age five until June 17, 2022, over two years after the emergence of the disease. *Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age*, U.S. FOOD AND DRUG ADMIN. (June 17, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children [https://perma.cc/E8JF-Y2TA].

211. *COVID-19 Vaccines for People Who Are Moderately or Severely Immunocompromised*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 22, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html [https://perma.cc/VH66-YGVT].

212. *People with Certain Medical Conditions*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 6, 2022), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html [https://perma.cc/4AYC-EBXV].

vulnerable the tools to protect themselves better positively impacts the overall health of the population.

The value of personal protective equipment in helping vulnerable individuals avoid infection has been amply demonstrated in the COVID-19 pandemic. Providing access to needed personal protective equipment not only helps the individual patient but also helps the public. If more individuals engage in measures to dampen the spread, like mask wearing for respiratory illnesses, then the spread of illness should be slowed. The overall rate of severe disease or death will decrease in parallel to enabling the most vulnerable to protect themselves. Both of these impacts may enable policymakers to rely less frequently or less heavily on measures like lockdowns or business restrictions, which are damaging in different ways.

While health insurance has traditionally focused on clinical interventions to treat disease or injury, medicine and health insurance have been evolving. Healthcare practitioners now focus not only on clinical interventions but also on more holistic measures of health. There is a greater focus on preventive care. Patients are increasingly screened for wellness measures. Clinical care increasingly considers the patient's social determinants of health. Health insurance has in many ways evolved in tandem with medicine, notably in the coverage of preventive care. This Article's proposal that health insurance ensures access to over-the-counter items necessary to protect a patient's health is part of this evolution.