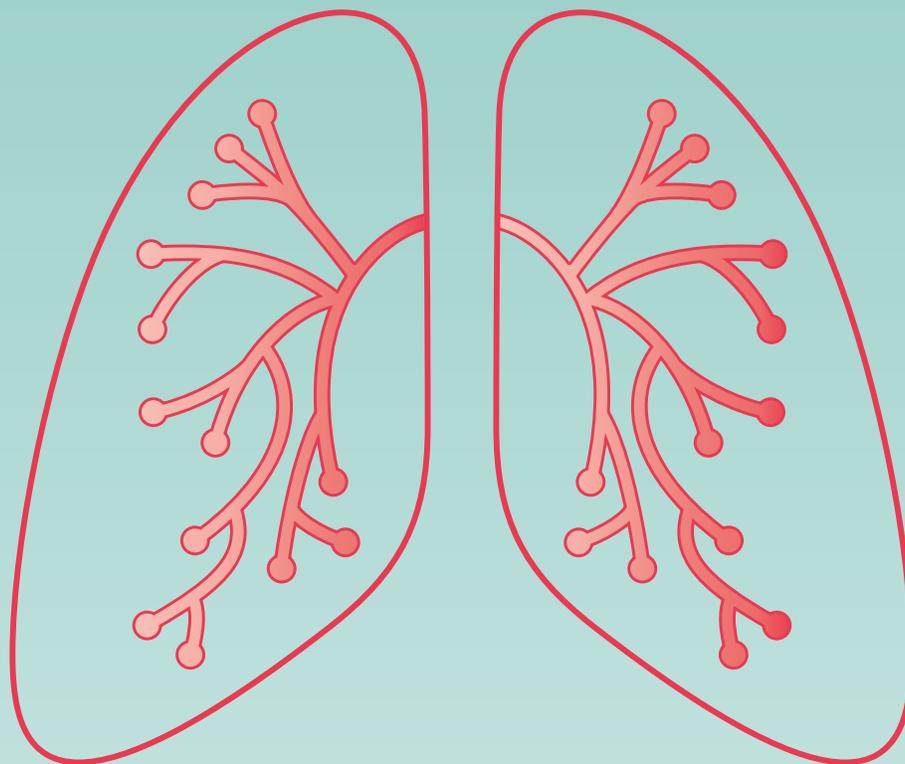


# Tobacco Cessation Medications

*Understanding Medicaid, Medicare, and Private Insurance Coverage*



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**CENTER for HEALTH LAW  
and POLICY INNOVATION**  
HARVARD LAW SCHOOL

## ABOUT THE AUTHORS

The Center for Health Law and Policy Innovation of Harvard Law School advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. CHLPI works with consumers, advocates, community-based organizations, health and social services professionals, food providers and producers, government officials, and others to expand access to high-quality health care and nutritious, affordable food; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective health care and food systems. CHLPI is a clinical teaching program of Harvard Law School and mentors students to become skilled, innovative, and thoughtful practitioners as well as leaders in health, public health, and food law and policy.

The LuCa National Training Network provides training and materials for primary care providers, as well as technical assistance for professionals who educate providers and other health care professionals on lung cancer prevention, early detection, treatment, and survivorship care. LuCa works with health systems, state cancer coalitions, provider organizations, and others interested in engaging providers around lung cancer topics, with a particular emphasis on screening and tobacco cessation.

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# INTRODUCTION / HOW TO USE THIS RESOURCE

Access to affordable preventive services like tobacco cessation medications can make a critical difference in the lives of individuals living with or at risk for lung cancer. However, health insurance coverage for preventive services can vary widely between insurance programs and individual insurers. This resource is designed to help health care providers, patients, and advocates navigate this complex coverage landscape. The resource is broken into the following four sections:

- **Part I: Overview of Insurance/Payer Coverage,**
- **Part II: Conducting Your Own Research,**
- **Part III: Frequently Asked Questions, and**
- **Part IV: Additional Resources**

**Part I** provides an overview of the current status of coverage for tobacco cessation medications for adults enrolled in Medicaid, Medicare, and private insurance plans. **Part II** then provides strategies for conducting additional research regarding these programs. **Part III** examines frequently asked questions related to insurance coverage and restrictions. Finally, **Part IV** provides a list of additional resources that readers can access to learn more about this topic.

***Please note that this resource outlines what coverage should look like based on current national requirements and guidance. Individual insurers may vary in their implementation of these requirements. To confirm coverage within a particular plan, contact the individual insurer.***

## I. OVERVIEW OF INSURANCE/PAYER COVERAGE

**Tobacco Cessation Medications:** Tobacco Cessation Medications are over-the-counter and prescription medications used to support patients in their efforts to quit tobacco use. FDA-approved tobacco cessation medications include: nicotine replacement therapies (patch, gum, inhaler, nasal spray, or lozenge), bupropion SR, and varenicline. For the purposes of this resource, we will be examining coverage of tobacco cessation medications for adults only.

This first section provides an overview of the current status of insurance coverage for these services based on current federal laws, regulations, and guidance. Where coverage is **not** uniform within a particular program, the overview chart states that coverage "**varies.**" In these situations, you will need to reach out to individual insurers (e.g., your state Medicaid program) to determine coverage.

| Insurer  | Coverage (Y/N) | Population Covered  | Cost-Sharing         | Details / Limitations   |
|--|----------------|---|----------------------|---|
| <b>Medicaid (Traditional)</b> <sup>1</sup>                     | Yes            | Adults who are not pregnant who currently use tobacco.                                    | Varies <sup>3</sup>  | <i>Should</i> include all prescription and over-the-counter tobacco cessation medications approved by FDA. <sup>5</sup>   |
| <b>Medicaid (Traditional—Pregnant Women)</b> <sup>2</sup>      | Yes            | Pregnant women who currently use tobacco.   | No <sup>4</sup>      | <i>Should</i> include all prescription and over-the-counter tobacco cessation medications approved by FDA. <sup>6</sup>   |
| <b>Medicaid (Expansion)</b> <sup>7</sup>                       | Yes            | Adults who are not pregnant who currently use tobacco.                                    | No <sup>8</sup>      | <p>The U.S. Departments of Health and Human Services, Labor, and Treasury have provided guidance indicating coverage that includes the following would be considered compliant with coverage requirements:</p> <ul style="list-style-type: none"> <li>· All prescription and over-the-counter tobacco cessation medications approved by FDA</li> <li>· For a 90-day treatment regimen, when prescribed by a health care provider</li> <li>· Without prior authorization</li> </ul> <p>However, the guidance leaves some room for variation, and so patients and providers should check with the individual plan to confirm coverage details.<sup>9</sup></p>  |
| <b>Original Medicare (Part D)</b> <sup>10</sup>                | Yes            | Individuals who receive prescription drug coverage through Medicare Part D.               | Varies <sup>11</sup> | Medicare Part D cover at least some prescription tobacco cessation medications, <sup>12</sup> but typically will not cover over-the-counter tobacco cessation medications. <sup>13</sup>  |
| <b>Medicare Advantage</b> <sup>14</sup>                        | Yes            | Individuals who receive prescription drug coverage through their Medicare Advantage plan. | Varies <sup>15</sup> | Medicare Advantage plans must generally follow Part D coverage rules and may choose to cover over-the-counter medications as supplemental benefits. <sup>16</sup>   |
| <b>Group / Individual (non-grandfathered)</b> <sup>17,18</sup> | Yes            | Adults who are not pregnant who currently use tobacco.                                    | No                   | <p>The U.S. Departments of Health and Human Services, Labor, and Treasury have provided guidance indicating coverage that includes the following would be considered compliant with coverage requirements:</p> <ul style="list-style-type: none"> <li>· All prescription and over-the-counter tobacco cessation medications approved by FDA</li> <li>· For a 90-day treatment regimen, when prescribed by a health care provider</li> <li>· Without prior authorization</li> </ul> <p>However, the guidance leaves some room for variation, and so patients and providers should check with the individual plan to confirm coverage details.<sup>19</sup></p> |
| <b>Short-Term Health Insurance Plans</b>                       | Varies         | Varies  | Varies               | Short-term health insurance plans are <u>not</u> considered individual health insurance plans and <u>not</u> subject to the Essential Health Benefits or preventive service coverage requirements of the Affordable Care Act. <sup>20</sup> Coverage and cost-sharing for tobacco cessation medications in these plans therefore may vary greatly.  |

## II. CONDUCTING YOUR OWN RESEARCH

### A. Medicaid

#### i. Program Overview

Medicaid is our nation's safety net health insurance program. Traditionally, Medicaid has provided health insurance coverage to low-income families, children, pregnant women, the elderly, and people with disabilities. Under the Affordable Care Act, states now also have the option to provide coverage to the Medicaid expansion population, which includes all adults with incomes up to 138% of the federal poverty level. While states that have chosen to expand coverage have generally tried to align coverage between their traditional and expansion populations, some distinctions remain.

#### ii. Research Strategies

Over time, medical advances and new legal requirements may alter the Medicaid coverage landscape. You can use the following strategies and resources to conduct your own research and determine the current status of coverage for tobacco cessation medications.

- **Drug Coverage for Traditional Medicaid:** Under Section 1927 of the Social Security Act, state Medicaid programs are generally required to cover all prescription drugs sold by manufacturers who have entered into a rebate agreement with HHS and/or the state for their traditional Medicaid population. Under this section, states may typically exclude over-the-counter drugs from coverage.<sup>21</sup> However, the section specifically prohibits states from excluding smoking cessation agents, including over-the-counter tobacco cessation medications.<sup>22</sup> Patients may need to meet prior authorization requirements in order to access tobacco cessation medications, and will generally need to receive a prescription, even for over-the-counter medications.
- **Medicaid Expansion Status by State:** States which elect to expand Medicaid coverage under the Affordable Care Act to adults with incomes up to 138% of the federal poverty level must abide by different requirements for that population. To determine whether your state has opted to expand Medicaid, you can visit the Kaiser Family Foundation website, which provides an [interactive map](#) of states which **have** elected to cover the Medicaid expansion population.
- **USPSTF Coverage Recommendations:** As a baseline, states must cover at least one tobacco cessation medication for Medicaid expansion populations (or the number of medications covered in the state's benchmark plan, if greater), based on rules regarding coverage of Essential Health Benefits in these plans.<sup>23</sup> However, rules regarding coverage for **preventive services** in Medicaid expansion plans build upon this baseline, likely making coverage of cessation medications more comprehensive. States **must** cover all services that have received an "A" or "B" rating from the United States Preventive Services Task Force (USPSTF) without cost-sharing for individuals in the Medicaid expansion population.<sup>24</sup> Currently, the USPSTF provides an "A" rating for its recommendation on "Tobacco Smoking Cessation in Adults . . . Behavioral and Pharmacotherapy Interventions." This recommendation states that clinicians should provide FDA-approved pharmacotherapy for cessation to non-pregnant adults who use tobacco. The recommendation does not explicitly state whether all cessation medications must be covered, but HHS has provided guidance encouraging states to do so in the past.<sup>25</sup>
  - **Finding USPSTF Recommendations:** You can stay up to date on USPSTF service recommendations by visiting [their website](#) and using the search feature to locate relevant recommendations. For example, searching for "tobacco" reveals the USPSTF recommendation for Tobacco Smoking Cessation, as well as information regarding ongoing efforts to update this recommendation.
  - **Note on Changes to USPSTF Recommendations:** If changes occur to a USPSTF recommendation, Medicaid expansion plans must reflect the change in plan years that begin one year after the new

recommendation is published.<sup>26</sup> For example, if the USPSTF were to update its recommendation for tobacco smoking cessation in adults in November 2019 and your state’s Medicaid expansion plan’s plan years begin on January 1<sup>st</sup>, the plan would have to reflect that new recommendation beginning on January 1, 2021.

- **Federal Regulations:** You can find additional high-level information on Medicaid coverage requirements in federal regulations. To find the relevant regulations, visit the electronic Code of Federal Regulations, select [“Title 42 – Public Health”](#) from the options provided, and follow the links to your desired subject. Most regulations related to Medicaid can be found in [Parts 430 – 456](#).
- **Individual Plan Information:** Based on the requirements of the Medicaid statute, Medicaid programs *should* cover all FDA-approved tobacco cessation medications for their traditional population. Similarly, as explained above, Medicaid expansion plans must provide coverage for *at least* some cessation medications. However, in practice, coverage has been known to vary and plans will often impose additional requirements (e.g., prior authorization, step therapy, etc.). **Therefore, it is particularly important for health care providers and patients to consult individual plan documents to confirm details and requirements for coverage of tobacco cessation medications.** Plan documents related to drug coverage are generally referred to as **“covered drug lists”** or **“formularies”** and should be available through your state Medicaid program or, if the patient is enrolled in managed care, the relevant Medicaid Managed Care Organization.
  - Some helpful compilations are also available online. For example, the American Lung Association has compiled an interactive resource which lays out all 50 states’ treatment of tobacco cessation (see *Additional Resources* below). However, keep in mind that these types of resources may become out-of-date and/or may be based on survey responses that are not consistently reliable. Therefore, it is always a good idea to confirm coverage with your state Medicaid agency and/or with individual Medicaid plans if your state uses Medicaid Managed Care Organizations (MMCOs) to deliver care.
- **Additional Resources**

| Insurer  | Resource   | Description  |
|----------|--|--|
| Medicaid | <a href="#">State Tobacco Cessation Coverage</a> <sup>27</sup> | The American Lung Association has compiled an interactive resource which describes tobacco cessation coverage under all 50 states’ Medicaid plans. |

## B. Medicare

### i. Program Overview

Medicare is the primary public health insurance program for elderly individuals in the United States. Specifically, Medicare provides insurance coverage for individuals aged 65 or older, some disabled individuals, and individuals living with end-stage renal disease (ESRD) or amyotrophic lateral sclerosis (ALS). Medicare is broken into four parts: Medicare Part A (hospital insurance), Medicare Part B (medical insurance), Medicare Part C (Medicare Advantage), and Medicare Part D (drug coverage).

Roughly two thirds of Medicare beneficiaries receive their Medicare coverage directly from the federal government (Original Medicare a/k/a Medicare Parts A & B). The remaining third receive their Medicare coverage from private insurers (Medicare Advantage a/k/a Medicare Part C). Medicare Advantage plans must generally cover all services covered in Original Medicare (except hospice services), making coverage very similar between these two programs. However, Medicare Advantage plans also have some flexibility to go beyond Original Medicare to cover additional services.

In order to receive coverage for drugs, Medicare enrollees must sign up for a standalone Medicare Part D prescription drug plan or a Medicare Advantage plan that includes drug coverage. Drug coverage and costs can vary significantly across plans. However, some baseline requirements do exist. For example, plans must typically cover at least two distinct drugs in each drug class.

Some individuals that have Original Medicare also have a Medicare Supplement (a/k/a Medigap) plan provided by a private insurer. These Supplement plans help to pay some of costs that Original Medicare doesn't cover (e.g., coinsurance, deductibles, etc.) and may include coverage for some services that Original Medicare does not cover.<sup>28</sup>

## ii. Research Strategies

Over time, medical advances and new legal requirements may alter the Medicare coverage landscape. You can use the following strategies and resources to conduct your own research and determine the current status of coverage for tobacco cessation medications.

- **Regulations:** Federal law and regulations require at least some coverage of tobacco cessation medications, but do not define which specific medications must be covered. As a baseline, federal law allows Medicare Part D to cover prescription, but not over-the-counter, tobacco cessation medications (though CMS provides some flexibility for plans to cover over-the-counter medications as administrative costs).<sup>29</sup> Federal regulations then generally require these plans to cover at least two drugs within each therapeutic category and class of Part D drugs.<sup>30</sup> Medicare Advantage Plans must also follow these rules and may cover over-the-counter tobacco cessation medications as supplemental benefits.<sup>31</sup>
  - **Finding Additional Information:** You can find additional high-level information on coverage requirements in federal Medicare regulations. If you wish to do further research, you can visit the electronic Code of Federal Regulations, select "[Title 42 – Public Health](#)" from the options provided, and follow the links to your desired subject. Regulations related to Medicare Part D can be found in [Part 423](#) regulations related to Medicare Advantage Plans can be found in [Part 422](#).
- **Medicare Manuals:** CMS publishes [electronic manuals](#) that provide additional details regarding coverage of services in the Medicare program. Manuals that may be particularly important to researching coverage of tobacco cessation medications include: the [Medicare Prescription Drug Benefit Manual \(CMS Pub. 100-18\)](#) and, for individuals in Medicare Advantage plans, the [Medicare Managed Care Manual, Ch. 4 – Benefits and Beneficiary Protections](#).
- **Individual Plan Information:** While all Medicare Advantage and Part D plans should provide *some* coverage of tobacco cessation medications, the exact drugs covered and requirements associated with coverage (e.g., prior authorization) will vary by plan. Therefore, it is particularly important for health care providers and patients to consult individual plan documents to confirm details and requirements for coverage of tobacco cessation medications. Plan documents related to drug coverage are generally referred to as "**covered drug lists**" or "**formularies**" and should be available through the individual plan.

## C. Private Insurance Plans - Group and Individual Insurance

### i. Program Overview

Group insurance plans are private plans which provide health insurance coverage to members of a group, which tend to be employees of a company or members of an organization. In contrast, individual insurance plans are private plans which are purchased directly by consumers, typically on a state or federal-run marketplace, and are not provided by an employer or other group.

While the benefits covered by group and individual plans can vary more broadly than in public insurance programs, the Affordable Care Act introduced new coverage requirements that create a uniform baseline of

preventive service coverage in almost all private plans.

## ii. Research Strategies

Over time, medical advances and new legal requirements may alter the private insurance coverage landscape. You can use the following strategies and resources to conduct your own research and determine the current status of coverage for tobacco cessation medications.

- **USPSTF Coverage:** Like Medicaid expansion plans, many private plans (specifically individual and small group plans) must cover at least one tobacco cessation medication (or more if more are covered in the state's benchmark plan) based on rules regarding coverage of Essential Health Benefits. However, rules regarding coverage of **preventive services** in private plans build upon this baseline, likely making coverage more comprehensive. Under the Affordable Care Act, individual and group plans generally **must** cover all "A" and "B" rated services without cost-sharing. Currently, the USPSTF provides an "A" rating for its recommendation on "Tobacco Smoking Cessation in Adults . . . Behavioral and Pharmacotherapy Interventions." This recommendation states that clinicians should provide FDA-approved pharmacotherapy for cessation to non-pregnant adults who use tobacco. The recommendation does not explicitly state whether all cessation medications must be covered, but HHS has provided guidance encouraging plans to do so in the past.<sup>32</sup>
  - **Finding USPSTF Recommendations:** You can stay up to date on USPSTF service recommendations by visiting [their website](#) and using the search feature to locate relevant recommendations. For example, searching for "tobacco" reveals the USPSTF recommendation for Tobacco Smoking Cessation, as well as information regarding ongoing efforts to update this recommendation.
  - **Note on Changes to USPSTF Recommendations:** If changes occur to a USPSTF recommendation, private plans must reflect the change in plan years that begin one year after the new recommendation is published.<sup>33</sup> For example, if the USPSTF were to update its recommendation for tobacco smoking cessation in adults in November 2019 and your insurer's plan years begin on January 1<sup>st</sup>, the plan would have to reflect that new recommendation beginning on January 1, 2021.
- **Individual Plan Information:** While individual and group plans should provide some coverage of tobacco cessation medications, the exact drugs covered and requirements associated with coverage (e.g., prior authorization) may vary by plan. Therefore, it is particularly important for health care providers and patients to consult individual plan documents to confirm details and requirements for coverage of tobacco cessation medications. Plan documents related to drug coverage are generally referred to as "**covered drug lists**" or "**formularies**" and should be available through the individual plan.
- **Grandfathered Status:** Group and individual insurance plans which existed at the time the Affordable Care Act was enacted in 2010 may be **exempt** from some of the Act's requirements, including the requirements to cover Essential Health Benefits and USPSTF "A" and "B" rated services. Federal regulations at [45 C.F.R. Section 147.140](#) lay out the events which cause a plan to lose grandfathered status. If you have further questions about particular plans, you should contact the plan administrator, as individual plans are required to disclose information related to grandfathered status.
- **Short-term Plans:** Short-term health plans are **not** considered individual insurance plans under the Affordable Care Act and are **exempt** from many of the Act's requirements, including the requirements to cover Essential Health Benefits and USPSTF "A" and "B" rated services.<sup>34</sup> Therefore, coverage and cost-sharing for tobacco cessation counseling will vary greatly in these plans. To determine coverage and cost-sharing in short-term plans, you will need to consult plan documents or contact the plan directly.

## III. FREQUENTLY ASKED QUESTIONS

### a. What if the Patient Lacks Insurance or Fails to Meet Eligibility Requirements?

Patients who lack coverage under the insurance regimes described in this resource, or who fail to meet the eligibility requirements of those insurance regimes will generally be required to pay for the services out of pocket.

### **b. What is Prior Authorization?**

Prior authorization is the process by which health care providers must obtain advanced approval from a health insurance plan before a prescribed procedure, service, or medication is delivered to the patient to qualify for payment coverage under the plan. Prior authorization requirements vary by plan. Therefore, to determine if a plan has a prior authorization requirement for any particular tobacco cessation medication, you should consult the individual plan materials and/or call the plan.

### **c. What if Tobacco Cessation Medications Are Delivered by an Out-of-Network or Non-Preferred Pharmacy?**

If a patient receives services from a pharmacy that is not part of their plan's network, they may face additional costs. For example, the Affordable Care Act does not require private plans to cover USPSTF "A" and "B" rated services that are provided out-of-network unless the plan does not have providers that can provide them in-network (in which case, the plan would be required to cover USPSTF services from out-of-network providers without cost-sharing<sup>35</sup>). Similarly, patients in Medicare Part D and Medicare Advantage plans may face additional cost-sharing requirements if they receive tobacco cessation medications outside of their plan's network or if the pharmacy is in-network but non-preferred.

## **IV. ADDITIONAL KEY RESOURCES**

To learn more about insurance coverage of tobacco cessation medications and related services, you can consult these additional resources developed by advocacy organizations, professional associations, and other experts.

| <b>Resource</b>  | <b>Description</b>  |
|--|---|
| <a href="#"><b>American Cancer Society Cancer Action Network:</b> Tobacco Cessation Insurance Coverage</a> | The American Cancer Society Cancer Action Network (ACS CAN) provides an overview of tobacco cessation insurance coverage and related issues, such as cost-sharing and prior authorization. ACS CAN also provides recommendations on policy changes to improve access to these services. |
| <a href="#"><b>American Lung Association:</b> State Tobacco Cessation Coverage</a>                         | ALA provides a state-by-state analysis of coverage of tobacco cessation services across state insurance programs including Medicaid, individual plans, and the state employee health plan.  |

# Endnotes

- <sup>1</sup> 42 U.S.C. § 1396r-8(d)(7)(A).
- <sup>2</sup> The Affordable Care Act imposed stricter requirements on states to cover tobacco cessation treatments for pregnant women. Section 4107 of the Affordable Care Act requires pregnant women be provided counseling and pharmacotherapy for tobacco cessation, which includes diagnostic, therapy, and counseling services, and pharmacotherapy, including FDA-approved prescription and non-prescription medications used for tobacco cessation. 42 U.S.C. §§ 1396d(a)(4)(D), (bb)(1).
- <sup>3</sup> Eliminating cost-sharing for the traditional Medicaid population is optional for states, which will receive a one-percent FMAP increase if they voluntarily enact a state plan amendment which covers and eliminates cost sharing for all “A” and “B” graded USPSTF services. *See* 42 U.S.C. § 1396d(b)(5). Note: This FMAP increase only applies to coverage of these “A” and “B” rated services.
- <sup>4</sup> 42 U.S.C. § 1396o(a)(2)(B), (b)(2)(B); 42 U.S.C. § 1396o-1(b)(3)(B)(iii).
- <sup>5</sup> *See* 42 U.S.C. § 1396r-8(d)(7)(A) (stating that tobacco cessation products cannot be excluded from coverage).
- <sup>6</sup> *See* 42 U.S.C. § 1396d(bb)(1); *see also* “State Medicaid Director Letter Re: New Medicaid Tobacco Cessation Services (SDL # 11-007),” Ctrs. for Medicare & Medicaid Svcs. (June 24, 2011), *available at* <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD11-007.pdf>.
- <sup>7</sup> 42 C.F.R. § 440.347(a)(9) (referencing Essential Health Benefit requirements in 45 C.F.R. § 156.115(a)(4) which reference preventive service requirements at 45 C.F.R. § 147.130(a)(1)(i)).
- <sup>8</sup> 78 Fed. Reg. 42159, 42226.
- <sup>9</sup> There remains some debate as to whether the USPSTF recommendation requires plans to cover all FDA-approved cessation medications, or if the plans may choose which cessation medications to cover. *See generally* “FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation,” U.S. Dep’t of Labor, 2-4 (Oct. 27, 2016), *available at* <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>. This guidance document raises the question of whether the recommended scope of coverage should be changed in light of a change to the USPSTF recommendation. However, the Dep’t of Labor does not appear to have issued updated guidance. Therefore, in practice, scope of coverage may vary based on the uncertainty from the most recent guidance.
- <sup>10</sup> 42 U.S.C. § 1395w-102(e)(2)(A).
- <sup>11</sup> 42 U.S.C. § 1395w-102(b), (c). Cost sharing for prescription drug coverage under Medicare Part D can vary widely.
- <sup>12</sup> 42 C.F.R. § 423.120(b)(2) (stating that Part D plans must cover at least 2 drugs within each therapeutic category and class of Part D drugs, unless the class only includes one Part D drug or the class includes only 2 Part D drugs and one is clinically superior; also stating that coverage must include “adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines”).
- <sup>13</sup> 42 U.S.C. § 1395w-102(e)(1)(A).
- <sup>14</sup> 42 U.S.C. § 1395w-102(e)(2)(A); 42 U.S.C. § 1395w-131(c)(1) (stating that Part D rules generally apply to prescription drug coverage provided under Medicare Advantage Prescription Drug plans).
- <sup>15</sup> 42 U.S.C. § 1395w-102(b), (c). Cost sharing for prescription drug coverage under Medicare Part D and Medicare Advantage Prescription Drug plans can vary widely.
- <sup>16</sup> “Medicare Managed Care Manual, Ch. 4 – Benefits and Beneficiary Protections,” Ctrs. For Medicare & Medicaid Svcs., §§ 30.3, 40 (Apr. 2016), *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>.
- <sup>17</sup> 42 U.S.C. § 300gg-13(a)(1).
- <sup>18</sup> Private insurance plans which maintain “grandfathered” status are not subject to many of the requirements of the Affordable Care Act. 42 U.S.C. § 18011(a). For a list of events which can cause a policy to lose its grandfathered status, *see* 45 C.F.R. § 147.140.
- <sup>19</sup> There remains some debate as to whether the USPSTF recommendation requires plans to cover all FDA-approved cessation medications, or if the plans may choose which cessation medications to cover. *See generally* “FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation,” U.S. Dep’t of Labor, 2-4 (Oct. 27, 2016), *available at* <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>. Therefore, in practice, scope of coverage may vary based on the uncertainty from the most recent guidance.
- <sup>20</sup> 42 U.S.C. 300gg-91(b)(5); *see also* K. Lucia et al., “State Regulation of Coverage Options Outside of the Affordable Care Act: Limiting the Risk of the Individual Market,” The Commonwealth Fund (Mar. 2018).
- <sup>21</sup> *See* 42 U.S.C. § 1396r-8(d)(2) (stating that nonprescription drugs may be restricted or excluded).
- <sup>22</sup> *See* 42 U.S.C. § 1396r-8(d)(7)(A) (stating that tobacco cessation products, including over-the-counter products, cannot be excluded from coverage).
- <sup>23</sup> *See* 42 C.F.R. § 440.347(a) (requiring Medicaid expansion plans to cover essential health benefits consistent with the requirements laid out for group and individual plans in 45 C.F.R. § 156); 45 C.F.R. § 156.122 (stating that to meet essential health benefits requirements, the plan must cover the greater of one drug in every United States Pharmacopeia (USO) category or class;

or the same number of prescription drugs in each category and class as the state's chosen essential health benefits benchmark plan).

- <sup>24</sup> 42 C.F.R. § 440.347(a)(9) (referencing Essential Health Benefit requirements in 45 C.F.R. § 156.115(a)(4) which reference preventive service requirements at 45 C.F.R. § 147.130(a)(1)(i)); 78 Fed. Reg. 42159, 42226 (incorporating the prohibition on cost-sharing).
- <sup>25</sup> There remains some debate as to whether the USPSTF recommendation requires plans to cover all FDA-approved cessation medications, or if the plans may choose which cessation medications to cover. *See generally* "FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation," U.S. Dep't of Labor, 2-4 (Oct. 27, 2016), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>. Therefore, in practice, scope of coverage may vary based on the uncertainty from the most recent guidance.
- <sup>26</sup> *See* 42 C.F.R. § 440.347(a) (requiring Medicaid expansion plans to cover essential health benefits consistent with the requirements laid out for group and individual plans in 45 C.F.R. § 156); 45 C.F.R. § 156.115(a)(4) (requiring essential health benefits to include coverage of preventive health services as described in 45 C.F.R. § 147.130); 45 C.F.R. § 147.130(b)(1) (stating that coverage must begin "for plan years . . . that begin on or after the date that is one year after the date the recommendation or guideline is issued").
- <sup>27</sup> *See* "State Tobacco Cessation Coverage," Am. Lung Ass'n, <http://www.lungusa2.org/cessation2/> (last visited July 5, 2019).
- <sup>28</sup> *See* "What's Medicare Supplement Insurance (Medigap)?," Medicare.gov, <https://www.medicare.gov/supplements-other-insurance/whats-medicare-supplement-insurance-medigap> (last visited Oct. 11, 2019).
- <sup>29</sup> 42 U.S.C. § 1395w-102(e)(1)(A), (e)(2)(A) *see* "Prescription Drug Benefit Manual - Chapter 7 - Medication Therapy Management and Quality Improvement Program," 60.2 (Feb. 2010), available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/Pub100\\_18.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/Pub100_18.pdf).
- <sup>30</sup> 42 C.F.R. § 423.120(b)(2) (stating that Part D plans must cover at least 2 drugs within each therapeutic category and class of Part D drugs, unless the class only includes one Part D drug or the class includes only 2 Part D drugs and one is clinically superior; also stating that coverage must include "adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines"); "USP Medicare Model Guidelines v7.0 (Categories and Classes)," United States Pharmacopeia, (Feb. 2017), available at <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines> (listing "Smoking Cessation Agents" as a class within the category "Anti-Addiction/Substance Abuse Treatment Agents"); "Medicare Prescription Drug Benefit Manual, Ch. 6 – Part D Drugs and Formulary Requirements," Ctrs. for Medicare & Medicaid Svcs., at Appendix D – The Most Commonly Prescribed Drug Classes for the Medicare Population (Jan. 2016), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.
- <sup>31</sup> "Medicare Managed Care Manual, Ch. 4 – Benefits and Beneficiary Protections," Ctrs. For Medicare & Medicaid Svcs., §§ 30.3, 40 (Apr. 2016), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>.
- <sup>32</sup> There remains some debate as to whether the USPSTF recommendation requires plans to cover all FDA-approved cessation medications, or if the plans may choose which cessation medications to cover. *See generally* "FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation," U.S. Dep't of Labor, 2-4 (Oct. 27, 2016), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>. Therefore, in practice, scope of coverage may vary based on the uncertainty from the most recent guidance.
- <sup>33</sup> *See* 45 C.F.R. § 156.115(a)(4) (requiring essential health benefits to include coverage of preventive health services as described in 45 C.F.R. § 147.130); 45 C.F.R. § 147.130(b)(1) (stating that coverage must begin "for plan years . . . that begin on or after the date that is one year after the date the recommendation or guideline is issued").
- <sup>34</sup> 42 U.S.C. 300gg-91(b)(5); *see also* K. Lucia et al., "State Regulation of Coverage Options Outside of the Affordable Care Act: Limiting the Risk of the Individual Market," The Commonwealth Fund (Mar. 2018).
- <sup>35</sup> 45 C.F.R. § 147.130(a)(3).

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