

# ARTICLE

## SAY WHAT? THE AFFORDABLE CARE ACT, MEDICARE, AND HEARING AIDS

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*One of the most common consequences of aging is hearing loss, representing the third most prevalent chronic medical condition among seniors. Empirical evidence links hearing loss to a variety of other medical conditions, including depression, falls, and cognitive problems. Additionally, there is a demonstrated relationship between hearing loss and dementia. And yet, most insurance programs do not cover the cost of hearing aids. Even Medicare, the federal insurance program for those aged sixty-five and over, statutorily excludes coverage of hearing aids, which cost between \$2,000 and \$7,000 a pair.*

*The Affordable Care Act (“ACA”), reflecting a radical departure from the goals embodied in the 1965 Medicare law, presents a lens for examining this issue anew. Numerous statutory provisions and the philosophy embodied in the ACA are useful catalysts for reform of the Medicare law. This Article elaborates on one specific provision of the ACA that could be utilized to authorize insurance coverage under the Medicare program. It also addresses other provisions in the ACA, including required preventive screenings and selected “Essential Health Benefits,” that, absent the Medicare exclusion, arguably would provide for such coverage. Acknowledging the tension between the ACA and Medicare law, this Article argues that the ACA is a useful tool for amending the Medicare law and eliminating this antiquated coverage exclusion. Finally, it suggests strategies for effectuating that result.*

“If we are lucky, we will all grow old. But how frightening to grow old and not be able to see clearly, hear distinctly . . . because we cannot afford the necessary medical appliances to aid our failing faculties.”<sup>1</sup>

### I. INTRODUCTION

Age-related hearing loss is the third most prevalent chronic medical condition among older adults.<sup>2</sup> And yet, most insurance programs do not

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<sup>1</sup> H.R. REP. NO. 78-385, at VI (1976).

<sup>2</sup> Patricia A. Tun et al., *Aging, Hearing Acuity, and the Attentional Costs of Effortful Listening*, 24(3) PSYCHOL. & AGING 761, 761–66 (2009). Hearing loss affects approximately forty-nine percent of those aged seventy and over, Derrick Lopez et al., *Falls, Injuries from Falls, Health Related Quality of Life and Mortality in Older Adults With Vision and Hearing Impairment—Is There a Gender Difference?*, 69(4) MATURITAS 359, 359 (2011), and twenty-five to fifty percent of those sixty-five and older, *Quick Statistics About Hearing*, NAT'L INST.

cover the cost of hearing aids. The devices are expensive, costing, in 2014, from \$2,200 to more than \$7,000 per pair, depending on the features and quality of the devices.<sup>3</sup> Unfortunately, Medicare, which provides health insurance to 46.3 million people ages sixty-five and over,<sup>4</sup> does not cover hearing aids because hearing aids, eyeglasses, and other similar devices were statutorily excluded in 1965 when the Medicare law was enacted.<sup>5</sup> Yet many Medicare beneficiaries cannot afford to pay for hearing aids out of pocket.<sup>6</sup> An increasingly small percentage of seniors have additional coverage through employer-sponsored retiree health plans, which occasionally offer limited coverage for hearing aids. Coverage in the Medicaid program, a joint federal-state partnership providing medical insurance for people with low incomes, also is quite limited and varies from state to state.

The failure of Medicare to provide any coverage for the costs of hearing aids, as well as the limited coverage provided in other insurance plans, is striking given the negative consequences of age-related hearing loss. Recent research demonstrates a relationship between hearing loss and dementia.<sup>7</sup> Hearing loss often results in increased isolation<sup>8</sup> and depression,<sup>9</sup> which frequently contribute to additional medical problems. There are demonstrated correlations between hearing loss and declines in “health related quality of life,”<sup>10</sup> increased incidents of falling,<sup>11</sup> accelerated cognitive decline,<sup>12</sup> and exacerbated age-related memory deficits.<sup>13</sup> Given the relationship between hearing loss and other medical problems, it is critical to develop advocacy

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ON DEAFNESS & OTHER COMMUNICATIVE DISORDERS, <http://www.nidcd.nih.gov/health/statistics/Pages/quick.aspx> [https://perma.cc/KT94-BJ7C] (last updated April 20, 2015).

<sup>3</sup> Ian Cropp, *Why Do Hearing Aids Cost So Much?*, AARP (Oct. 3, 2014), <http://www.aarp.org/health/conditions-treatments/info-05-2011/hearing-aids-cost.html> [https://perma.cc/R98L-SKZJ]. Over seventy-five percent of patients are fitted for two hearing aids. FREDERICK N. MARTIN & JOHN GREER CLARK, *INTRODUCTION TO AUDIOLOGY* 371 (12th ed. 2015). The average costs of mid-level hearing aids range from \$4,400 to \$4,500 a pair. Cropp, *supra* note 3.

<sup>4</sup> Juliette Cubanski et al., *A Primer on Medicare: Key Facts about the Medicare Program and the People it Covers*, KAISER FAM. FOUND. (Mar. 20, 2015), <http://kff.org/medicare/report/a-primer-on-medicare-key-facts-about-the-medicare-program-and-the-people-it-covers/> [https://perma.cc/C9GT-ZWE4].

<sup>5</sup> See S. REP. NO. 89-404, at 1989 (1965).

<sup>6</sup> Half of all people on Medicare in 2013 had incomes below \$23,500 per year. See Cubanski et al., *supra* note 4.

<sup>7</sup> See Frank R. Lin et al., *Hearing Loss and Incident Dementia*, 68(2) ARCHIVES OF NEUROLOGY 214, 214–20 (2011).

<sup>8</sup> See Frank R. Lin et al., *Hearing Loss and Cognition in the Baltimore Longitudinal Study of Aging*, 25(6) NEUROPSYCHOLOGY 763, 768 (2011) (“Communication impairments caused by hearing loss can lead to social isolation and loneliness in older adults.”).

<sup>9</sup> See Bamini Gopinath et al., *Hearing Handicap, Rather than Measured Hearing Impairment, Predicts Poorer Quality of Life Over 10 Years in Older Adults*, 72 MATURITAS 146, 146 (2012).

<sup>10</sup> See Lopez et al., *supra* note 2, at 359.

<sup>11</sup> See *id.*; see also Wade Chien & Frank R. Lin, *Prevalence of Hearing Aid Use Among Older Adults in the United States*, 172(3) JAMA INTERNAL MED. 292, 292 (2012).

<sup>12</sup> See Frank R. Lin et al., *Hearing Loss and Cognitive Decline Among Older Adults*, 173(4) JAMA INTERNAL MED. 293, 293 (2013).

<sup>13</sup> See generally Tun et al., *supra* note 2.

strategies to assist seniors forced either to pay for hearing aids out of pocket or to simply go without.<sup>14</sup>

The passage of the Affordable Care Act (“ACA”)<sup>15</sup> offers an exciting opportunity for such hearing aid advocacy. The ACA does not alter basic Medicare coverage policies nor eliminate the statutory exclusion of coverage of hearing aids.<sup>16</sup> However, if one examines the ACA in the absence of current Medicare law, numerous provisions could otherwise be interpreted to mandate insurance coverage of hearing screenings and hearing aids. One provision in the ACA authorizes the Secretary of Health and Human Services to test innovative service delivery models that could be utilized to provide coverage for hearing aids.<sup>17</sup> Other relevant provisions include those requiring general preventive screenings, the “Welcome to Medicare” visit, annual preventive visits, and the “Essential Health Benefit” provisions requiring depression screenings and rehabilitative and habilitative services. Thus, the ACA provides an opportunity to deliver coverage under the Medicare program on an experimental basis and a platform from which to advocate amending the Medicare statute, thereby promoting consistency with both the preventive care philosophy and provisions of the ACA. This Article will expound on these arguments for insurance coverage of hearing aids, focusing primarily on Medicare, the largest provider of health insurance for seniors,<sup>18</sup> and will suggest strategies for effectuating that result.

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<sup>14</sup> While insurance coverage for hearing aids is one way to improve hearing health, other proposals have been generated. Most notably, the President’s Council of Advisors on Science and Technology (“PCAST”), acknowledging the high cost of hearing aids, the absence of adequate insurance coverage, and the failure of costs to decline as other technologies become less expensive, made numerous recommendations to increase the availability of hearing devices. See generally Letter from PCAST to Barack Obama, President of the United States (Oct. 2015), [https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast\\_hearing\\_tech\\_letterreport\\_final3.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final3.pdf) [<https://perma.cc/3243-7EJF>]. PCAST’s recommendations include the following: (1) Permit the sale of hearing aids over the counter; (2) Reduce regulatory controls; (3) Modify Federal Trade Commission regulations to encourage competition among manufacturers and dispensers; and (4) Permit the sale of Personal Sound Amplification Products (“PSAPs”) for the use of hearing assistance. One particular recommendation included the withdrawal of the Federal Drug Administration’s November 7, 2013 draft guidance on PSAPs. *Id.* at 8. This guidance has already been withdrawn, and a request for comments on the guidance has been issued. See generally Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products, 83 Fed. Reg. 786 (Jan. 7, 2016).

<sup>15</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

<sup>16</sup> See 42 U.S.C.A. § 1395y(a)(7) (West 2015); see also Michael J. DeBoer, *Medicare Coverage Policy and Decision Making, Preventive Services, and Comparative Effectiveness Research Before and After the Affordable Care Act*, 7 J. HEALTH & BIOMEDICAL L. 493, 495 (2012).

<sup>17</sup> 42 U.S.C.A. § 1315a (a)(1) (West 2015) (“The purpose of the CMI [Center for Medicare and Medicaid Innovation] is to test innovative payment and service delivery models to reduce program expenditures under the applicable subchapters while preserving or enhancing the quality of care furnished to individuals under such subchapters. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).”).

<sup>18</sup> Cubanski et al., *supra* note 4.

Part II provides an overview of those affected by age-related hearing loss, a description of sensorineural hearing loss, and a summary of corrective devices and their usage. Part III outlines the costs of hearing aids, summarizes health insurance options for seniors, and offers a glimpse of life for seniors living in poverty. Part IV addresses the relationship between untreated hearing loss and other medical problems among the elderly. Part V argues that the ACA provision authorizing innovative projects to improve quality and reduce costs can and should be used to expand coverage of hearing aids. It also identifies several other sections of the ACA that are useful catalysts for advocating amendment of the Medicare law to provide this coverage. Additionally, it addresses coverage under the Medicaid program and private insurance policies in light of the ACA. Finally, Part VI recommends specific strategies to effectuate this result. Given an estimated twenty-three million older adults with untreated hearing loss,<sup>19</sup> providing insurance coverage for hearing devices is imperative.<sup>20</sup>

## II. OVERVIEW OF AGE-RELATED HEARING LOSS

### A. *Wide-Spread Prevalence of Presbycusis*

Age-related hearing loss, known as presbycusis,<sup>21</sup> affects an estimated twenty-five to forty percent of the U.S. population sixty-five and older.<sup>22</sup> Its prevalence rises with age, with an estimated forty-nine percent of those seventy and older experiencing hearing loss,<sup>23</sup> and an estimated eighty percent of those eighty and older experiencing it.<sup>24</sup> In the United States, the preva-

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<sup>19</sup> Chien & Lin, *supra* note 11, at 293.

<sup>20</sup> This article addresses presbycusis, age-related hearing loss, and not the concerns of those who are born into a deaf community. *See, e.g.,* Megan A. Jones, *Deafness as Culture: A Psychological Perspective*, 22(2) *DISABILITY STUD. Q.*, 51–60 (2002). Those who become deaf later in life may be characterized as “physically deaf” and those who are born into a deaf community as “culturally Deaf.” Many people who become deaf later in life are culturally hearing; their culture includes spoken language, with their thoughts, speech and opinions centered around the world they inhabited prior to becoming deaf. *Id.* For some but not all of those who are culturally Deaf, their native language is signed, not spoken. *Id.* These communities have varying perspectives and concerns; however, the concerns of the culturally Deaf community regarding hearing devices and insurance are beyond the scope of this article.

<sup>21</sup> *See generally* George A. Gates & John H. Mills, *Presbycusis*, 366 *LANCET* 1111 (2005).

<sup>22</sup> *Quick Statistics About Hearing*, *supra* note 2.

<sup>23</sup> Lopez et al., *supra* note 2, at 359; *see also* Heather E. Whitson & Frank R. Lin, *Hearing and Vision Care for Older Adults: Sensing a Need to Update Medicare Policies*, 321(17) *JAMA* 1739, 1739 (2014) (stating that “[t]he prevalence of hearing loss doubles with every age decade”).

<sup>24</sup> Roger Chou et al., *Screening Adults Aged 50 Years or Older for Hearing Loss: A Review of the Evidence for the U.S. Preventive Services Task Force*, 154(5) *ANNALS INTERNAL MED.* 347, 347 (2011). Different studies report different statistics, with variations likely attributable to varying definitions of hearing impairment and age, and different methods of assessment, including some subjective testing. *See id.* at 354. Some currently fear we face an impending epidemic of hearing impairments. *See, e.g., Untreated Hearing Loss in Adults—A*

lence of hearing loss has been found to be higher among men.<sup>25</sup> A study of participants with an average age of seventy-eight found the incidence of hearing loss was approximately thirty percent among males and thirteen percent among females.<sup>26</sup> Hearing loss prevalence was higher among study participants with hypertension, diabetes, and heavy tobacco use.<sup>27</sup>

Despite the high rate of presbycusis, fewer than one in three U.S. adults aged seventy and older who could benefit from hearing aids have ever used them.<sup>28</sup> Hearing aids are expensive, with prices of fitted models ranging from approximately \$2,200 to over \$7,000 per pair.<sup>29</sup> Other impediments to obtaining a hearing device include stigma, negative associations with age and disability, and cosmetic concerns.<sup>30</sup> Many people deny their hearing loss, particularly because age-related hearing loss happens so gradually.<sup>31</sup> The average time between initial diagnosis and treatment is over ten years.<sup>32</sup>

Hearing loss statistics are similar in other western countries.<sup>33</sup> Worldwide, there is a noticeable correlation between hearing aid use and level of

*Growing National Epidemic*, AM. SPEECH-LANGUAGE-HEARING ASS'N, <http://www.asha.org/aud/articles/untreated-hearing-loss-in-adults/> [<https://perma.cc/9RDL-2FCR>].

<sup>25</sup> Yuri Agrawal et al., *Prevalence of Hearing Loss and Differences by Demographic Characteristics Among U.S. Adults*, 168(14) JAMA INTERNAL MED. 1522, 1525 (2008).

<sup>26</sup> Lopez et al., *supra* note 2, at 361. Males are affected more at high sound frequencies, STANLEY A. GELFAND, ESSENTIALS OF AUDIOLOGY 193 (3rd ed. 2009), with women showing greater hearing loss in the low frequencies, DEBRA BUSACCO, AUDIOLOGIC INTERPRETATION ACROSS THE LIFESPAN 135 (2010).

<sup>27</sup> Agrawal et al., *supra* note 25, at 1525.

<sup>28</sup> *Quick Statistics About Hearing*, *supra* note 2. According to the Hearing Loss Association of America (“HLAA”), eighty percent of those who could benefit from hearing aids do not get them. *Hearing Health Care and Insurance*, HEARING LOSS ASS'N AMERICA, <http://www.hearingloss.org/content/hearing-health-care-and-insurance> [<https://perma.cc/9FCC-JEN5>]. Of those between ages twenty to sixty-five who could benefit from hearing aids, only sixteen percent have ever used them. *Quick Statistics About Hearing*, *supra* note 2.

<sup>29</sup> Cropp, *supra* note 3.

<sup>30</sup> Mark Ross, *Why People Won't Wear Hearing Aids*, REHABILITATION ENGINEERING RES. CTR. ON HEARING ENHANCEMENT, [http://www.hearingresearch.org/ross/hearing\\_aids/why\\_people\\_wont\\_wear\\_hearing\\_aids.php](http://www.hearingresearch.org/ross/hearing_aids/why_people_wont_wear_hearing_aids.php) [<https://perma.cc/J3SX-K969>] (last updated July 1, 2013) (explaining that those with hearing loss often choose not to obtain or wear hearing aids due to societal and public attitudes around them; such attitudes may include age- or disability-related stigma, the perception that hearing aids are not worth the hefty price tag, or the belief that hearing aids simply will not be effective).

<sup>31</sup> See, e.g., Susan Seliger, *Why Won't They Get Hearing Aids?*, N.Y. TIMES: NEW OLD AGE (Apr. 5, 2012, 11:53 AM), [http://newoldage.blogs.nytimes.com/2012/04/05/why-wont-they-get-hearing-aids/?\\_php=true&\\_type=blogs&\\_r=2](http://newoldage.blogs.nytimes.com/2012/04/05/why-wont-they-get-hearing-aids/?_php=true&_type=blogs&_r=2) [<https://perma.cc/QH6J-CVJR>]; Samuel Trychin, *Why Don't People Who Need Them Get Hearing Aids*, U. FLORIDA (2003), <http://users.clas.ufl.edu/mcolburn/Web-links/Nursing%20Lecture/Why%20Don't%20People%20Who%20Need%20Them%20Get%20Hearing%20Aids.htm> [<https://perma.cc/X6U3-DSZL>].

<sup>32</sup> *Untreated Hearing Loss in Adults—A Growing National Epidemic*, *supra* note 24.

<sup>33</sup> See, e.g., *Seniors*, SPEECH-LANGUAGE & AUDIOLOGY CAN., <http://sac-oac.ca/public/seniors> [<https://perma.cc/KJ87-6JWS>]; Francesco Cacciatore et al., *Quality of Life Determinants and Hearing Function in an Elderly Population: Osservatorio Geriatrico Campano Study Group*, 45(6) GERONTOLOGY 323, 323 (1999) (noting the very high prevalence of hearing impairment among the elderly in Italy). It is difficult to compare presbycusis rates around the world due to incomplete data, varying thresholds for defining hearing impairment, and the use of variable age groups. See Colin Mathers et al., *Global Burden of Hearing Loss in the Year 2000 2–6* (World Health Org., Geneva, GBD 2000 Working Paper, 2003), <http://www.who.int/>

government assistance.<sup>34</sup> For example, in Australia, which has a high subsidy rate, nearly forty percent of the hearing-impaired population uses hearing aids.<sup>35</sup> In Europe, the highest rates of hearing aid use are in Denmark, Norway, the United Kingdom, the Netherlands, and Sweden—all countries with high subsidy rates.<sup>36</sup> Use has been found to correlate not only with standard of living, but also with “accessibility to hearing health care, subsidy levels, and general historical factors.”<sup>37</sup> Evidence that the level of subsidy increases hearing aid use in other Western countries offers useful lessons for the United States as it explores the ramifications of untreated presbycusis.

### B. Hearing Loss Basics

Presbycusis is a sensorineural hearing loss caused by cochlear<sup>38</sup> and/or neural damage.<sup>39</sup> It is the result of various kinds of physiological degeneration caused by the normal aging process plus the accumulated effects of noise exposure, chemicals (particularly from medications), medical disorders and their treatment, and genetics.<sup>40</sup> Both cochlear and neural damage are permanent; neither medicine nor surgery can replace missing or damaged

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healthinfo/statistics/bod\_hearingloss.pdf [https://perma.cc/C2KL-C3WU]. Consequently, it is also difficult to compare hearing aid use. *See, e.g.,* Nikolai Bisgaard, *An International Perspective*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 39, 39–42 (2014), <http://www.nap.edu/read/18735/chapter/1#v> [https://perma.cc/44UE-96PW].

<sup>34</sup> *See* Bisgaard, *An International Perspective*, *supra* note 33, at 40–41; *see also* Nikolai Bisgaard, *Hearing Industry Perspectives for EU Funded Hearing Research*, HEARCOM (2009), [http://www.hearcom.info/lenya/hearcom/authoring/about/DisseminationandExploitation/Workshop/5\\_Nikolai\\_Bisgaard\\_Industry-perspectives.pdf](http://www.hearcom.info/lenya/hearcom/authoring/about/DisseminationandExploitation/Workshop/5_Nikolai_Bisgaard_Industry-perspectives.pdf) [https://perma.cc/GQC7-X3HJ] (presentation from the Workshop on Hearing Screening and New Technologies).

<sup>35</sup> Bisgaard, *Hearing Industry Perspectives for EU Funded Hearing Research*, *supra* note 34, at 9.

<sup>36</sup> *See id.* at 11; *see also* Christine Cassel et al., *Policy Solutions for Better Hearing*, 315(6) JAMA 553, 553 (2016) (noting that hearing devices are included in basic health coverage in the United Kingdom, Denmark, and Switzerland).

<sup>37</sup> Bisgaard, *An International Perspective*, *supra* note 33, at 40. In developing countries, the usage rate is less than one percent. Mathers et al., *supra* note 33, at 14. As one industry expert stated, “If you live in a developing country and get some money, hearing aids are not the first thing you think about.” Bisgaard, *An International Perspective*, *supra* note 33, at 40.

<sup>38</sup> The cochlea is the part of the inner ear that translates noise vibrations into nerve impulses, which are then sent to the brain. *Cochlea*, FREE MED. DICTIONARY, <http://medical-dictionary.thefreedictionary.com/cochlea> [https://perma.cc/C4M3-NHYQ].

<sup>39</sup> GELFAND, *supra* note 26, at 159; *see also* BUSACCO, *supra* note 26, at 3.

<sup>40</sup> GELFAND, *supra* note 26, at 186, 193. Hearing loss from chemicals is known as ototoxicity. *See* BUSACCO, *supra* note 26, at 131 (“Elderly adults tend to take numerous medications for chronic health conditions, which can result in ototoxicity.”). Audiologists have identified various types of presbycusis, with some seniors having more than one type. For a full discussion of the various types, *see* GELFAND, *supra* note 26, at 194–96.

hair cells, and neurons do not regenerate.<sup>41</sup> The degree of hearing loss ranges from mild to profound<sup>42</sup> and may be unilateral or bilateral.<sup>43</sup>

Sensorineural hearing losses due to presbycusis typically result in hearing loss in the higher frequencies. High frequency acoustic cues in speech are necessary for understanding most consonant sounds and higher octaves; with high frequency hearing loss, certain sounds are rendered barely audible or inaudible.<sup>44</sup> Therefore, the most common complaint of those with presbycusis is that they can hear speech, but that it is unclear or hard to understand. Speech is even harder to decipher when noise or competing sounds are present.<sup>45</sup>

Seniors also may experience mixed hearing loss, a combination of a sensorineural loss and conductive loss in the same ear. “Conductive” hearing loss impairs the transmission of sounds from the environment to the cochlea, resulting in a weaker signal and therefore diminished volume.<sup>46</sup> Although the conductive portion of the hearing loss can often be treated with medical and/or surgical intervention or amplification devices,<sup>47</sup> the sensorineural loss will remain.<sup>48</sup>

### C. *Treatments for Age-Related Hearing Loss*

The first step in evaluating potential presbycusis is a hearing screening during a routine physical. If a senior fails the screening, the physician typically refers the patient to an audiologist or otologist, who conducts a diag-

<sup>41</sup> GELFAND, *supra* note 26, at 159; *see also* BUSACCO, *supra* note 26, at 3 (“For this type of hearing loss, there is usually no medical or surgical intervention to restore hearing sensitivity to within normal limits.”).

<sup>42</sup> BUSACCO, *supra* note 26, at 3. For further discussion of how hearing loss is measured, *see* *Hearing and Hearing Loss*, AM. ACAD. AUDIOLOGY, [www.howyourhearing.org/hearing-loss.html](http://www.howyourhearing.org/hearing-loss.html) [<https://perma.cc/3ZSD-YHTU>] (indicating that hearing loss is measured in decibels: the higher the decibel number, the greater the degree of hearing loss).

<sup>43</sup> BUSACCO, *supra* note 26, at 2, 135.

<sup>44</sup> GELFAND, *supra* note 26, at 159. For a discussion of high frequency hearing loss, *see*, for example, Debbie Clason, *Understanding high-frequency hearing loss*, HEALTHY HEARING (May 12, 2015), <http://www.healthyhearing.com/report/52448-Understanding-high-frequency-hearing-loss> [<https://perma.cc/8FKW-L7MM>]; Ryan Crawford, *What Is High Frequency Hearing Loss*, HEARING REHAB CTR. (Oct. 29, 2012), <http://www.hearingrehabcenter.com/what-is-high-frequency-hearing-loss/> [<https://perma.cc/3AWM-ZMJD>].

<sup>45</sup> GELFAND, *supra* note 26, at 193; *see also* BUSACCO, *supra* note 26, at 135 (“Older adults typically report difficulty understanding speech in a variety of communication environments especially in the presence of background noise, reverberation, and listening at a distance”). For people with cochlear disorders many sounds are too soft to hear adequately or too loud to hear comfortably, GELFAND, *supra* note 26, at 159, resulting in hearing impaired people asking you to “speak up” and then asking you to “stop shouting” when you do, *id.* at 159–60. Those with severe-to-profound degrees of sensorineural loss will not be able to hear speech, including their own speech, without amplification. The inability to monitor one’s own speech can lead to aberrations in vocal pitch and loudness, as well as articulation errors. *Id.*

<sup>46</sup> BUSACCO, *supra* note 26, at 3; GELFAND, *supra* note 26, at 161.

<sup>47</sup> BUSACCO, *supra* note 26, at 3; GELFAND, *supra* note 26, at 161.

<sup>48</sup> BUSACCO, *supra* note 26, at 3–4.

nostic hearing test to determine the appropriate treatment.<sup>49</sup> If the tests are ordered by a physician “for the purpose of obtaining information necessary for the physician’s diagnostic medical evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem,” Medicare will cover the costs of the testing.<sup>50</sup> The assessment includes a test to determine hearing thresholds at different frequencies, or pitches, measured in hertz, and the loudness of the sound, measured in decibels.<sup>51</sup> It also includes an analysis of both the particular situations in which the patient is unable to hear and the patient’s communication requirements,<sup>52</sup> as well as social, emotional, occupational, and health issues.<sup>53</sup> Other considerations in measuring a hearing handicap are how the hearing loss restricts participation in day-to-day activities and otherwise affects health-related quality of life.<sup>54</sup> Treatment possibilities include a hearing aid, cochlear implant, bone-anchored hearing device, and modified communication strategies. The treatment is customized for the patient. If a device is implemented, the patient will require annual evaluations to maintain maximum device effectiveness.

The initial goal for a person who has presbycusis is to increase the intensities of sounds so that they become audible, maximizing the audibility of conversational speech without making the amplified signal uncomfortably loud.<sup>55</sup> Hearing aids offer one mechanism to do this. Today, most hearing

<sup>49</sup> For discussion of the tensions among various treating professionals, see *infra* text accompanying notes 324–333.

<sup>50</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE BENEFIT POLICY MANUAL, CHAPTER 15 100 (Rev. 212, Nov. 6, 2015), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf> [<https://perma.cc/U6YP-MJR2>]; see also DEP’T OF HEALTH & HUMAN SERVS. & CTRS. FOR MEDICARE & MEDICAID SERVS., CMS MANUAL SYSTEM, TRANSMITTAL 132, CHANGE REQUEST 6447, PUB 100-02 MEDICARE 9 (Sept. 3, 2010), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R132BP.pdf> [<https://perma.cc/9SWV-LW82>]; *infra* text accompanying notes 331–336 (discussing the legislative proposal to eliminate the physician-referral requirement). For a discussion of the types of testing that should be conducted, see, for example, Theresa Hnath Chisolm, *The Spectrum of Hearing Impairment and Interventions*, in INST. OF MED. & NAT’L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 31, 31–36 (2014), <http://www.nap.edu/read/18735/chapter/5> [<https://perma.cc/GM7Z-GY88>].

<sup>51</sup> See, e.g., *The Audiogram*, AM. SPEECH-LANGUAGE HEARING ASS’N, <http://www.asha.org/public/hearing/Audiogram/> [<https://perma.cc/7WXJ-U82Z>]. The record of these test results is called an Audiogram. *Id.* Human ears show differing sensitivities to different frequencies. A human ear is most sensitive to frequencies in the 1000 to 4000 Hz range, with men’s fundamental vocal frequency averaging about 85–150 Hz and women’s about 175–250 Hz. MARTIN & CLARK, *supra* note 3, at 41, 48.

<sup>52</sup> GELFAND, *supra* note 26, at 445.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* (citing Michael Valente et al., *Guidelines for the Audiologic Management of Adult Hearing Impairment*, AM. ACAD. AUDIOLOGY (2006), [http://audiology-web.s3.amazonaws.com/migrated/haguidelines.pdf\\_53994876e92e42.70908344.pdf](http://audiology-web.s3.amazonaws.com/migrated/haguidelines.pdf_53994876e92e42.70908344.pdf) [<https://perma.cc/3L9S-XCJH>]; Carole Johnson & Jeffrey Danhauer, *Health-Related Quality of Life Benefits of Amplification in Adults*, 18(5) AUDIOLOGY TODAY 28, 28–31 (2006)). Amplification is said to improve health-related quality of life by mitigating the social and psychological impact of hearing impairment for older adults. GELFAND, *supra* note 26, at 445.

<sup>55</sup> GELFAND, *supra* note 26, at 426, 450.

aids dispensed in the United States are digital, offering many adaptive functions, including sophisticated compression schemes, feedback cancellation, noise reduction, switching between directional and omnidirectional modes, and programs with different amplification strategies (e.g., quiet room, noisy environment, with music, etc.), to name a few.<sup>56</sup> Most hearing aids are battery powered and programs can be adjusted with a switch on the instrument or a remote control device.<sup>57</sup> Some hearing aids contain a telecoil, which links it to other assistive technology, connecting the listener directly to the source of the sound while eliminating most background noise.<sup>58</sup>

Typically, hearing aids are worn either behind or in the ear.<sup>59</sup> Behind-the-ear (“BTE”) instruments now represent over seventy percent of the hearing aids dispensed in the United States,<sup>60</sup> although in-the-ear (“ITE”) hearing aids may offer both cosmetic and acoustic benefits for some patients.<sup>61</sup>

Other assisted devices, including cochlear implants and bone-anchored hearing aids (“BAHA”), are surgically implanted. Cochlear implants are recommended only if the loss is so severe that the patient cannot benefit from traditional hearing aids.<sup>62</sup> These implants include internal components that are surgically inserted and external components, such as a microphone, which are worn outside of the body.<sup>63</sup> An external speech processor picks up sounds, which are transmitted to a receiver that converts them to electrical impulses eventually sent to the brain.<sup>64</sup> A cochlear implant is programmed for the individual patient.<sup>65</sup> Candidates for a cochlear implant must have working auditory fibers and an absence of medical problems that could com-

<sup>56</sup> *Id.* at 431.

<sup>57</sup> *Id.* at 426, 431.

<sup>58</sup> For an explanation of telecoils, see, for example, HEARING LOSS ASS'N OF AM., THE TELECOIL 2, [http://www.hearingloss.org/sites/default/files/docs/HLAA\\_Telecoil\\_Brochure.pdf](http://www.hearingloss.org/sites/default/files/docs/HLAA_Telecoil_Brochure.pdf) [<https://perma.cc/5UBM-E5V5>]. Often the telecoil is used with a “hearing loop” which enables sound to be picked up electromagnetically and transmitted to the telecoil. *See id.* The telecoil is activated by a t-switch on the hearing aid or cochlear implant which allows the user to switch between the telecoil and the microphone, or use both simultaneously. GELFAND, *supra* note 26, at 428.

<sup>59</sup> GELFAND, *supra* note 26, at 428. There are also body-level devices, used for the most severe hearing losses. *Id.* Today’s ear-level hearing devices are able to incorporate many of the advantages of the body-level devices and avoid the cosmetic and other problems presented by the body-level devices. *Id.* (citing Karl E. Strom, *The Hearing Care Market at the Turn of the 21st Century*, 7(3) HEARING REV. 8 (2000)).

<sup>60</sup> *See* MARTIN & CLARK, *supra* note 3, at 372.

<sup>61</sup> GELFAND, *supra* note 26, at 430.

<sup>62</sup> *See* MARTIN & CLARK, *supra* note 3, at 378; *see also* JoNel Aleccia, *Older Ears Hear Again with Cochlear Implants*, NBCNEWS (Oct. 2, 2008, 8:30 AM), <http://www.nbcnews.com/id/26980383/ns/health-aging/t/older-ears-hear-again-cochlear-implants/#.VMq2lmjF82s> [<https://perma.cc/5XZL-7W82>] (reporting a growing use of cochlear implants among seniors).

<sup>63</sup> GELFAND, *supra* note 26, at 453.

<sup>64</sup> *See, e.g., Cochlear Implants*, NAT’L INST. ON DEAFNESS & OTHER COMM’N DISORDERS, <http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx> [<https://perma.cc/3A47-K2YR>]. For a more technically precise explanation, *see* MARTIN & CLARK, *supra* note 3, at 379.

<sup>65</sup> GELFAND, *supra* note 26, at 453–55.

plicate surgery.<sup>66</sup> Those with dementia are not candidates for cochlear implants, given that the dementia interferes with the individual's ability to learn to use the device.<sup>67</sup> While cochlear implants may be effective for addressing severe hearing loss, they raise myriad other issues, leading some advocates in the disability community to oppose their use.<sup>68</sup>

The BAHA is anchored in the skull with a titanium screw,<sup>69</sup> allowing sound to be conducted through the bone instead of the middle ear.<sup>70</sup> A BAHA typically is used to treat conductive and mixed hearing losses, and therefore is not used to treat presbycusis alone.<sup>71</sup>

Despite the recommendations of hearing health professionals for individual assessments and customization of devices, personal sound amplification products ("PSAPs") are proliferating and may assist some with hearing loss. The U.S. Food and Drug Administration ("FDA") currently considers PSAPs to be devices for use by those without hearing loss, and therefore, at the present time, the FDA does not regulate PSAPs as hearing aids.<sup>72</sup> How-

<sup>66</sup> *Id.* at 455.

<sup>67</sup> *See, e.g.,* Sandra Young, *Hope for Hearing*, CNN (Dec. 18, 2012, 12:12 PM), <http://www.cnn.com/2012/12/28/health/cochlear-implants/> [<https://perma.cc/MHE7-ZT9F>] (noting that age is not a factor in determining eligibility, providing the candidate is healthy enough to undergo the surgery and does not have dementia, which would interfere with the use of the device). Despite these requirements, an increasing number of seniors are obtaining cochlear implants and experiencing cognitive benefits in addition to enhanced hearing. *See, e.g.,* Isabelle Mosnier et al., *Improvement of Cognitive Function After Cochlear Implantation in Elderly Patients*, 141(5) JAMA OTOLARYNGOLOGY—HEAD & NECK SURGERY 442–50 (2015); Aleccia, *supra* note 62 (reporting a growing use of cochlear implants among seniors).

<sup>68</sup> *See, e.g.,* Allegra Ringo, *Understanding Deafness: Not Everyone Wants to be 'Fixed'*, ATLANTIC (Aug. 9, 2013), <http://www.theatlantic.com/health/archive/2013/08/understanding-deafness-not-everyone-wants-to-be-fixed/278527> [<https://perma.cc/4H9A-JPP9>] (explaining that those who consider themselves members of the Deaf community view American Sign Language as their primary method of communication, and do not perceive deafness as a deficit to be fixed via surgical insertion of a medical device such as a cochlear implant).

<sup>69</sup> *See* MARYANNE TATE MALTBY & PAMELA KNIGHT, *AUDIOLOGY: AN INTRODUCTION FOR TEACHERS AND OTHER PROFESSIONALS* 48, 50 (2000).

<sup>70</sup> *See Bone Anchored Devices*, U. MD. MED. CTR., <http://umm.edu/programs/hearing/services/bone-anchored-devices#what> [<https://perma.cc/D33C-SK42>].

<sup>71</sup> *See Bone Anchored Devices, supra* note 70. The BAHA is relevant for this discussion largely due to proposed regulations that would have eliminated Medicare coverage. The proposed regulations were ultimately rejected. Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 66,120, 66,241–427 (Nov. 6, 2014) (codified at 42 C.F.R. § 411.15(d)(2)); *see also* Susan Thomas, *CMS rules to continue Medicare coverage of Osseointegrated Implants*, AM. COCHLEAR IMPLANT ALLIANCE (Nov. 3, 2014), <http://www.acialliance.org/news/200864/CMS-rules-to-continue-Medicare-coverage-of-Osseointegrated-Implants.htm> [<https://perma.cc/J256-F9TD>].

<sup>72</sup> *See Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products—Draft Guidance for Industry and Food and Drug Administration Staff*, FDA (Nov. 7, 2013), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm373461.htm> [<https://perma.cc/5BGR-R4P6>] (explaining that the FDA "regulates electronic products that emit sonic vibrations, such as sound amplification equipment"). However, the FDA recently reopened the comment period for these guidelines to address the "accessibility, affordability, and use of hearing aids and PSAPs." *Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Reopening of the Comment Period*, 81 Fed. Reg.

ever, the PSAPs are marketed to those with hearing loss, reportedly are helpful in amplifying sound,<sup>73</sup> and are recommended by some as a less expensive alternative for those with mild-to-moderate age-related hearing loss.<sup>74</sup> Recent technological developments enable them to be used with Bluetooth and smart phone technology.<sup>75</sup> Hearing health professionals are concerned, however, that more serious health problems are overlooked in the absence of a hearing assessment, that the devices merely amplify sound and are inadequate to meet hearing needs, and that they do not address potential underlying causes of hearing difficulties.<sup>76</sup>

Those with presbycusis also may be assisted with nontechnical interventions, such as enhanced communication strategies, problem-solving approaches, relaxation techniques, and techniques for families and partners to utilize when communicating with seniors with hearing loss.<sup>77</sup> Group-based audiological rehabilitation programs have proven particularly effective, and these trainings may be useful both to those with sophisticated tools such as cochlear implants and to those without assistive listening devices.<sup>78</sup>

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786, 787 (Jan. 7, 2016); *see also* Eric A. Mann, *Current FDA Standards*, in INST. OF MED. & NAT'L RES. COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 48, 51 (2014), <http://www.nap.edu/read/18735/chapter/6> [<https://perma.cc/XA9K-F9HL>] (noting the “gap between a PSAP and a hearing aid is essentially narrowing to nothing . . . it is how you market it and how you label it”).

<sup>73</sup> *See, e.g.*, Mark Ross, *Personal Sound Amplification Products (PSAPs) Versus Hearing Aids*, REHABILITATION ENGINEERING RES. CTR. ON HEARING ENHANCEMENT, [http://www.hearingresearch.org/ross/hearing\\_aids/psaps\\_vs\\_hearing\\_aids.php](http://www.hearingresearch.org/ross/hearing_aids/psaps_vs_hearing_aids.php) [<https://perma.cc/Q5NG-GXV9>] (last updated July 1, 2013).

<sup>74</sup> *See, e.g.*, Letter from PCAST, *supra* note 14, at 7 (noting that “the distinction between a PSAP and a hearing aid . . . is not clear, and there are many people with mild hearing impairment who can benefit from amplification by headphones and other devices, including PSAPs”).

<sup>75</sup> *See* Cathy Gandel, *Not Ready for a Hearing Aid but Need a Little Help?*, AARP (May 27, 2015), <http://www.aarp.org/health/conditions-treatments/info-2015/hearing-amplifiers-psaps.html> [<https://perma.cc/997F-EZM8>].

<sup>76</sup> *See* Debbie Clason, *The case against personal sound amplification devices*, HEALTHY HEARING (Mar. 28, 2014), <http://www.healthyhearing.com/report/51934-The-case-against-personal-sound-amplification-devices> [<https://perma.cc/58g6-JF97>]. Physician and researcher Frank Lin is increasingly supportive of PSAPs, and notes that the gap between these devices and hearing aids is narrowing and asks how these devices can be more accessible to consumers. *See* Mann, *supra* note 72, at 51. Examples of other evolving uses of technology in the hearing field include smart phones functioning as hearing aids, computerized phone-based auditory testing and training, and the use of “teleaudiology” to answer patient questions and even fine-tune a hearing aid. *See* Gabrielle Saunders, *Teleaudiology*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 61, 61 (2014), <http://www.nap.edu/read/18735/chapter/7#61> [<https://perma.cc/9JNT-46YT>] (defining teleaudiology as “the delivery of audiology services and information via telecommunications technologies”).

<sup>77</sup> *See, e.g.*, Chisolm, *supra* note 50, at 34–35.

<sup>78</sup> *See id.* For an example of a communication strategy training program for those with cochlear implants, *see generally* SUSAN BINZER, COCHLEAR AMS., IMPROVING UNDERSTANDINGS WITH COMMUNICATION STRATEGIES, <http://hope.cochlearamericas.com/sites/default/files/resources/FUN2041%20Adult%20Communication%20Strategies%20TP.pdf> [<https://perma.cc/DFU3-QB9M>]. *See generally* Whitson & Lin, *supra* note 23 (supporting CMS reimbursement for unbundled hearing services such as therapeutic rehabilitation).

### III. IMPEDIMENTS TO HEARING AID USE AMONG SENIORS

#### A. Costs

Seniors in need of hearing devices fail to use them for numerous reasons.<sup>79</sup> One common explanation is cost. Hearing devices are expensive. In 2014, a pair of fitted hearing aids ranged from approximately \$2,200 to over \$7,000, with the average costs of mid-level hearing aids falling between \$4,400 and \$4,500 a pair.<sup>80</sup> High costs typically are attributed to materials, research expenses, and marketing.<sup>81</sup> If purchased from a hearing clinic, costs tend to be two and a half times higher than wholesale prices due to the need for expensive equipment, salaries, overhead, licenses, insurance, and staff time spent on adjustments and fittings, all of which are typically included.<sup>82</sup> A *Consumer Reports* study indicated that the average mark-up was 117% in those cases where the wholesale price could be determined.<sup>83</sup> Some argue that this system of “bundled” pricing, which include the costs of fitting and

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<sup>79</sup> See *supra* notes 33–39 and accompanying text.

<sup>80</sup> Cropp, *supra* note 3. Over seventy-five percent of patients are fitted for two hearing aids. MARTIN & CLARK, *supra* note 3, at 371; see also Paul Dybala, *Hearing aid prices*, HEALTHY HEARING (Oct. 16, 2015), <http://www.healthyhearing.com/help/hearing-aids/prices> [<https://perma.cc/Y3AS-BPLQ>] (indicating that costs range from \$1,600–\$8,000 a pair and that the average cost is \$4,800 per pair); Amy M. Donahue et al., *NIDCD Research Working Group on Accessible and Affordable Hearing Health Care*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 77, 78–79 (2014), <http://www.nap.edu/read/18735/chapter/8> [<https://perma.cc/W2JD-7FC5>] (“[A]mong nonadopters [of hearing aids], cost is cited as the primary reason for not getting a hearing aid. Two-thirds of these people said that they would get a hearing aid if insurance or other programs provided 100 percent coverage . . .”). Requests for information about costs and affordability are the most frequent inquiries to the HLAA office, and their most frequently visited website page is the financial aid fact sheet for hearing technologies. *Hearing Health Care and Insurance*, *supra* note 28.

<sup>81</sup> Cropp, *supra* note 3.

<sup>82</sup> See *id.* A breakdown of the actual costs of hearing aids shows materials costing only a small percentage of the total price, with research constituting about one-third. *Id.* Some question the value of offering hearing aids as a “bundled” service that includes ongoing fittings and adjustments, arguing that bundling results in devices that cost more and users paying for services they may not need or want. See, e.g., Margaret Wallhagen, *The Current U.S. Hearing Health Care Model*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 36, 38 (2014), <http://www.nap.edu/read/18735/chapter/5#36> [<https://perma.cc/MW5P-VJY4>] (“Many audiologists are arguing that costs should be unbundled because the cost of a hearing aid is not really the cost of the hearing aid by itself but the cost of the hearing aid plus that of surrounding services.”).

<sup>83</sup> *Hearing aid buying guide*, CONSUMER REPORTS (Sept. 2015), <http://www.consumerreports.org/cro/hearing-aids/buying-guide.htm> [<https://perma.cc/8TRM-P7A5>]. Another hearing aid buying guide is available from the Better Hearing Institute. Sergei Kochkin, *Guide to Buying Hearing Aids*, BETTER HEARING INST., <http://www.betterhearing.org/hearingpedia/hearing-aids/guide-buying-hearing-aids> [<https://perma.cc/Q5K4-X8WD>]. For the story of one consumer’s adventure replacing her hearing aid, see Tricia Romano, *The Hunt For an Affordable Hearing Aid*, N.Y. TIMES: WELL (Oct. 22, 2012, 4:53 PM), [http://well.blogs.nytimes.com/2012/10/22/the-hunt-for-an-affordable-hearing-aid/?\\_r=0](http://well.blogs.nytimes.com/2012/10/22/the-hunt-for-an-affordable-hearing-aid/?_r=0) [<https://perma.cc/SY3P-53Q2>].

follow-up, is “of uncertain benefit and prevents patients from distinguishing between sources of expense.”<sup>84</sup>

Costco Wholesale,<sup>85</sup> Audicus, and “hi HealthInnovations”<sup>86</sup> have now entered the hearing aid market, providing lower cost devices;<sup>87</sup> however, these devices do not include services such as “assessment, repair, earwax removal, counseling, and aural rehabilitation,” services typically included when devices are purchased through a clinic.<sup>88</sup> Some question these merchants’ ability to provide devices tailored to an individual senior’s needs,<sup>89</sup> and critics are concerned that such devices fail to maximize patients’ full hearing potential and that their purchase may result in related medical problems going undetected.<sup>90</sup> Others, such as the President’s Council of Advisors on Science and Technology (“PCAST”), see the current requirement of a medical evaluation (or patient waiver) prior to obtaining a hearing device as an unnecessary barrier to hearing assistance.<sup>91</sup>

### B. Insurance Coverage of Hearing Devices

Despite the high costs of hearing aids, an overview of the health insurance landscape for seniors reveals that little coverage is available and further explains why these lower cost options are attractive to seniors. Medicare, the

<sup>84</sup> Whitson & Lin, *supra* note 23, at 1740; *see also* Letter from PCAST, *supra* note 14, at 3 (recommending a number of reforms to make hearing devices more accessible and affordable, including the unbundling of services).

<sup>85</sup> For a list of the products available at Costco Wholesale, *see* *Hearing Aid Styles*, COSTCO WHOLESALE, <http://www.costco.com/hearing-aid-styles.html> [<https://perma.cc/6Q2W-EBL2>].

<sup>86</sup> “hi HealthInnovations” is a subsidiary of United Healthcare. For a list of the products available from “hi HealthInnovations,” *see* *Products*, HI HEALTHINNOVATIONS, <https://www.hihealthinnovations.com/page/productlanding> [<https://perma.cc/FJ6U-W55A>].

<sup>87</sup> For a discussion of hearing aid costs, *see* Ed Belcher, *Why Does a Hearing Aid Cost Six Times the Price of an iPad?*, AUDICUS (Oct. 16, 2014), <https://audicus.com/why-does-a-hearing-aid-cost-six-times-more-than-an-ipad> [<https://perma.cc/33AY-YNGF>]. In this blog posted on the provider Audicus’ website—which advertises “the best hearing aids with the lowest markups”—Belcher concludes that the average markup of hearing aids sold by dispensing businesses is 300% and that the production costs of a hearing aid are typically only 8% of the total costs, with the remaining costs going to dispensing fees, administrative salaries, and markup. *Id.* A different analysis concludes that a hearing aid that would have sold for \$230 in 1952 would sell in today’s dollars for \$2,000, much less than the current average price. *See* Ashlee Vance, *Why do Hearing Aids Cost More than Laptops?*, BLOOMBERG BUSINESSWEEK (June 6, 2013, 6:26 PM), <http://www.businessweek.com/articles/2013-06-06/why-do-hearing-aids-cost-more-than-laptops> [<https://perma.cc/8D2J-8J8B>].

<sup>88</sup> Robert Burkard, *The Changing Health Care System*, in INST. OF MED. & NAT’L RESEARCH COUNCIL, *HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 75*, 75 (2014), <http://www.nap.edu/read/18735/chapter/8#75> [<https://perma.cc/TH8J-B5WB>] (noting there is no mechanism to provide these services elsewhere for those who purchase hearing aids directly from retailers).

<sup>89</sup> *See* Gyl A. Kasewurm, *An Independent Practice’s Guide to Battling Big Box Retail and Commoditization in Hearing Healthcare*, HEARING REV. (June 20, 2014), <http://www.hearingreview.com/2014/06/independent-practices-guide-battling-big-box-retail-commoditization-hearing-healthcare> [<https://perma.cc/F9E9-8UE7>].

<sup>90</sup> MARTIN & CLARK, *supra* note 3, at 489.

<sup>91</sup> Letter from PCAST, *supra* note 14, at 4–5.

primary insurer for most seniors, provides health insurance to 46.3 million people ages sixty-five and older.<sup>92</sup> In 2013, Medicare expenditures constituted more than twenty percent of total health expenditures in the United States and in 2014, fourteen percent of the federal budget.<sup>93</sup>

The Medicare program is comprised of several “Parts.” Most people age sixty-five and older are entitled to Medicare Part A, which primarily covers hospital benefits, but also covers some short nursing home stays, hospice benefits, and limited home health care.<sup>94</sup> Seniors also may enroll in Medicare Part B, which covers physician services, outpatient services, preventive services, and limited home health care.<sup>95</sup> As an alternative to Medicare Part B, seniors may elect to enroll in a Medicare Advantage Plan, also known as Medicare Part C. Such plans provide all of the services covered by “traditional” Medicare Parts A and B.<sup>96</sup> In 2015, thirty-one percent of Medicare beneficiaries were enrolled in Medicare Advantage Plans.<sup>97</sup>

Given that Medicare has high deductibles and covers only some of the health care expenses seniors face,<sup>98</sup> seniors often choose one of several routes to supplement Medicare. One option is to purchase supplemental coverage in the form of a “Medigap” policy.<sup>99</sup> Twenty-three percent of Medicare beneficiaries have Medigap policies.<sup>100</sup> However, such policies are expensive, averaging \$183 per month in 2010.<sup>101</sup> Another option, but one available to fewer and fewer seniors, is an employer-sponsored retiree health

<sup>92</sup> Cubanski et al., *supra* note 4. An additional nine million people with disabilities under age sixty-five also have Medicare coverage. *Id.* Before the enactment of Medicare in 1965, approximately half of all seniors had no medical insurance at all. *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Medicare at a Glance*, KAISER FAM. FOUND. (Sept. 2, 2014), <http://kff.org/medicare/fact-sheet/medicare-at-a-glance-fact-sheet> [<https://perma.cc/C5HH-KEBY>].

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* Medicare Advantage Plans, available through private insurers, follow either a health maintenance organization model (“HMO”) or provide services through a preferred provider organization (“PPO”). *Id.* For a discussion of the challenges of understanding enrollment in and coverage through Medicare Part B, see generally STACY SANDERS, MEDICARE RIGHTS CTR., MEDICARE PART B ENROLLMENT: PITFALLS, PROBLEMS AND PENALTIES (Nov. 2014), <http://www.medicarerights.org/pdf/PartB-Enrollment-Pitfalls-Problems-and-Penalties.pdf> [<https://perma.cc/4M6L-ASL5>].

<sup>97</sup> *Medicare at a Glance*, *supra* note 94. The number of Medicare Advantage Plan enrollees has increased fifty percent since the passage of the ACA. Patricia Neuman et al., *Medicare Advantage and Traditional Medicare: Is the Balance Tipping?*, KAISER FAM. FOUND. (Oct. 20, 2015), <http://kff.org/report-section/medicare-advantage-and-traditional-medicare-is-the-balance-tipping-issue-brief> [<https://perma.cc/C377-Q5LK>]. Seniors who elect not to enroll in any Medicare-related physician coverage plan and later choose to do so are subject to a penalty that can have long-lasting effects. See Bob Rosenblatt, *Don’t Mess Up Your Medicare Part B*, HELPWITHAGING.COM, <http://helpwithaging.com/health-insurance/dont-mess-up-your-medicare-part-b> [<https://perma.cc/ZA5X-NBCW>].

<sup>98</sup> See *Medicare at a Glance*, *supra* note 94.

<sup>99</sup> See *id.*

<sup>100</sup> Gretchen Jacobson et al., *Medigap Reform: Setting the Context for Understanding Recent Proposals*, KAISER FAM. FOUND. (Jan. 13, 2014), <http://kff.org/medicare/issue-brief/medigap-reform-setting-the-context> [<https://perma.cc/WV63-5FNX>].

<sup>101</sup> *Id.*

plan.<sup>102</sup> The percentage of large employers offering such plans dropped from sixty-eight percent in 1988 to twenty-eight percent in 2013.<sup>103</sup> Today, fewer than one in five American workers have employer-sponsored, retiree health insurance.<sup>104</sup>

Finally, seniors with very low incomes and modest assets may be eligible for assistance under the Medicaid program. Medicaid covers the costs of Medicare premiums, some cost sharing, and long-term care.<sup>105</sup> However, only 4.6 million seniors are eligible for Medicaid,<sup>106</sup> a small percentage of the 46.3 million seniors enrolled in the Medicare program.<sup>107</sup> Under the ACA, states have the option of expanding their Medicaid programs to cover all persons with incomes less than 138% of the federal poverty level.<sup>108</sup> In those states that provide expansion, which currently number thirty-one, se-

<sup>102</sup> Such plans are subject to the Medicare coordination of benefits rules that determine whether Medicare or the private plan is the primary insurer. *See, e.g.*, SANDERS, *supra* note 96, at 5. “Coordination of benefits” is defined as “a sharing of costs and coverage by two or more health plans. When a Medicare beneficiary has a second form of insurance, Medicare will act as either a primary or a secondary payer. Primary insurance always pays first, and secondary insurance pays after the primary insurance, typically covering cost sharing and services not covered by the primary insurer, depending on the rules of the policy.” *Id.* For Medicare recipients with an employer-sponsored retiree health plan, the employer-sponsored plan is secondary to Medicare. *Id.*

<sup>103</sup> Frank McArdle et al., *Retiree Health Benefits at the Crossroads*, KAISER FAM. FOUND. (Apr. 14, 2014), <http://kff.org/report-section/retiree-health-benefits-at-the-crossroads-overview-of-health-benefits-for-pre-65-and-medicare-eligible-retirees> [https://perma.cc/RSF7-7WWK]. “If this trend continues, fewer future Medicare beneficiaries will have retiree health benefits and more will be responsible for paying Medicare premiums and out-of-pocket costs.” Gretchen Jacobson et al., *Wide Disparities in the Income and Assets of People on Medicare by Race and Ethnicity: Now and in the Future*, KAISER FAM. FOUND. (Sept. 20, 2013), <http://kff.org/medicare/report/wide-disparities-in-the-income-and-assets-of-people-on-medicare-by-race-and-ethnicity-now-and-in-the-future> [https://perma.cc/ZRD4-SDE8].

<sup>104</sup> McArdle et al., *supra* note 103. Retiree health insurance historically has been more common among large employers, state and local governments, and certain industries. *Id.* Those employers that do offer coverage are increasingly exploring ways to reduce costs. *Id.*

<sup>105</sup> *See Seniors & Medicare and Medicaid Enrollees*, MEDICAID.GOV, <https://www.medicare.gov/medicaid-chip-program-information/by-population/medicare-medicare-enrollees-dual-eligibles/seniors-and-medicare-and-medicare-enrollees.html> [https://perma.cc/283Q-MFUY].

<sup>106</sup> *Id.*

<sup>107</sup> Cubanski et al., *supra* note 4.

<sup>108</sup> 42 U.S.C. § 1396d(y)(1) (2012), as limited by *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012) (holding that Medicaid expansion under the ACA could not be compulsory for the states). For information regarding state Medicaid expansion, see, for example, *Medicaid Expansion & What It Means for You*, HEALTHCARE.GOV, <https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/> [https://perma.cc/8UWS-ZKP2]. For an analysis of the extent of Medicaid expansion and of the coverage gap resulting from the *Sebelius* decision, see Rachel Garfield & Anthony Damico, *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid—An Update*, KAISER FAM. FOUND. (Jan. 21, 2016), <http://kff.org/health-reform/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicare-an-update> [https://perma.cc/RW5U-H2QP]. Of those unable to secure coverage due to states’ decisions to opt out of Medicaid expansion, “over half are middle-aged (age 35 to 54) or near elderly (age 55 to 64). Adults of these ages are likely to have increasing health needs, and research has demonstrated that uninsured people in this age range may leave health needs untreated until they become eligible for Medicare at age 65.” *Id.*

niors between the ages of sixty and sixty-five may have additional insurance coverage under Medicaid.<sup>109</sup>

This glance at the health insurance landscape for seniors reveals the critical need for Medicare to cover the costs of hearing aids. Currently, the vast majority of seniors have no insurance coverage for hearing aids at all. Those with Medicare Advantage Plans may have a modicum of coverage.<sup>110</sup> The small percentage of seniors fortunate enough to have employer-sponsored retiree health insurance also have limited coverage.<sup>111</sup> For the nineteen percent of Medicare beneficiaries eligible for Medicaid, coverage is very limited and varies by state.<sup>112</sup> Only twenty-nine states cover any portion of the costs of hearing aids through Medicaid.<sup>113</sup> Medigap policies typically do not cover hearing aids.<sup>114</sup>

In contrast with hearing aids, cochlear implants, which cost over \$40,000 per implant,<sup>115</sup> are typically covered through Medicare, Medicaid, and private insurance plans.<sup>116</sup> The BAHA device is similarly covered, under the rationale that it is a prosthesis that replaces, rather than augments, hearing.<sup>117</sup> PSAPs are sold directly to consumers, are not considered medical devices, and are therefore not covered by insurance.<sup>118</sup>

<sup>109</sup> Julia Paradise, *Medicaid Moving Forward*, KAISER FAM. FOUND. (Mar. 9, 2015), <http://kff.org/health-reform/issue-brief/medicaid-moving-forward> [<https://perma.cc/M5HC-7XKM>].

<sup>110</sup> See, e.g., *Medicare and Hearing Aids*, EHEALTHMEDICARE.COM, <http://www.ehealthmedicare.com/about-medicare/hearing-aids> [<https://perma.cc/RV6N-MVUT>].

<sup>111</sup> See *id.*

<sup>112</sup> See *Medicaid Regulations*, HEARING LOSS ASS'N AMERICA (Jan. 2015), <http://www.hearingloss.org/content/medicaid-regulations> [<https://perma.cc/FF9S-UVDS>].

<sup>113</sup> See *id.* The problem of limited coverage is exacerbated by the challenge of identifying a medical provider willing to accept Medicaid. For a general description of this problem, see Elizabeth Renter, *You've Got Medicaid—Why Can't You See the Doctor?*, U.S. NEWS & WORLD REP. (May 26, 2015, 9:00 AM), <http://health.usnews.com/health-news/health-insurance/articles/2015/05/26/youve-got-medicaid-why-cant-you-see-the-doctor> [<https://perma.cc/N66Q-ZWZG>].

<sup>114</sup> *Medicare and Hearing Aids*, *supra* note 110.

<sup>115</sup> See, e.g., *Cochlear Implants Frequently Asked Questions*, AM. SPEECH-LANGUAGE-HEARING ASS'N, [www.asha.org/public/hearing/Cochlear-Implant-Frequently-Asked-Questions](http://www.asha.org/public/hearing/Cochlear-Implant-Frequently-Asked-Questions) [<https://perma.cc/L7H5-MPQ4>]. This cost includes the device, surgery, and rehabilitation. See *id.*

<sup>116</sup> See *id.*

<sup>117</sup> See generally Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 66,120, 66,241–427 (Nov. 6, 2014), codified at 42 C.F.R. § 411.15(d)(2) (2015) (discussing CMS's final decision that BAHAs remain covered by Medicare, despite earlier proposal to eliminate coverage).

<sup>118</sup> The FDA, seeking “to better understand how we can overcome the barriers to access and spur the development of devices that compensate for impaired hearing,” has reopened its comment period on a draft guidance that “clarifies the difference in regulatory requirements between hearing aids and PSAPs.” Press Release, FDA, *The FDA Engages Stakeholders on Opportunities to Improve Hearing Aid Usage and Innovation* (Jan. 6, 2016), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm480239.htm> [<https://perma.cc/JX8G-CW9C>]; Mann, *supra* note 72, at 49; *Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products—Draft Guidance for Industry and Food and Drug Administration Staff*, FDA (Nov. 7, 2013), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm373461.htm> [<https://perma.cc/4BS4-YRNU>] (ex-

## C. Poverty Among Seniors

Compounding the problem of inadequate insurance coverage for hearing aids is the high rate of poverty among seniors.<sup>119</sup> In 2013, 9.5% of those aged sixty-five and over lived in poverty,<sup>120</sup> with the percentage increasing with age.<sup>121</sup> Thirty-four percent of seniors have incomes below two hundred percent of the official measure of poverty.<sup>122</sup> The causes of increased poverty are multifaceted, and include reductions in income due to a decreasing percentage of seniors with pensions,<sup>123</sup> an absence of wage increases in the final years of employment,<sup>124</sup> and caregiving duties for the seniors' own parents that may result in seniors retiring earlier than planned.<sup>125</sup> Additionally, until recently, a depressed housing market resulted in seniors with less equity in

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plaining that the FDA “regulates electronic products that emit sonic vibrations, such as sound amplification equipment”). See generally Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Reopening of the Comment Period, 81 Fed. Reg. 786 (Jan. 7, 2016).

<sup>119</sup> See, e.g., Mary Borrowman, *Understanding Elderly Poverty in the U.S.: Alternative Measures of Elderly Deprivation* 3 (Schwartz Ctr. for Econ. Policy Analysis, Working Paper No. 2012-3, 2012), [http://www.economicpolicyresearch.org/images/docs/research/inequality\\_poverty/WP%202012-3%20Mary%20Borrowman.pdf](http://www.economicpolicyresearch.org/images/docs/research/inequality_poverty/WP%202012-3%20Mary%20Borrowman.pdf) [<https://perma.cc/3YDB-MDCL>]; Juliette Cubanski et al., *Poverty Among Seniors: An Updated Analysis of National and State Level Poverty Rates Under the Official and Supplemental Poverty Measures*, KAISER FAM. FOUND. (June 10, 2015), <http://kff.org/medicare/issue-brief/poverty-among-seniors-an-updated-analysis-of-national-and-state-level-poverty-rates-under-the-official-and-supplemental-poverty-measures> [<https://perma.cc/7S6T-G9A6>].

<sup>120</sup> U.S. CENSUS BUREAU, REP. NO. P60-249, INCOME AND POVERTY IN THE U.S.: 2013, at 12 (2014), <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-249.pdf> [<https://perma.cc/B9A2-6WLQ>].

<sup>121</sup> Cubanski et al., *supra* note 119. The 2013 poverty level for one person was \$11,173. U.S. CENSUS BUREAU, *supra* note 120, at 43. In 2011, the Census Bureau developed a supplemental measure of poverty, which deducts the costs of health expenses. Cubanski et al., *supra* note 119. Under the supplemental measure, fifteen percent of those aged 65 and over lived in poverty in 2013. *Id.*

<sup>122</sup> *Income Security and the Elderly: Securing Gains Made in the War on Poverty: Hearing Before the S. Special Comm. on Aging*, 113th Cong. (2014) (statement of Patricia Neuman, Sc.D., Director, Program on Medicare Policy and Senior Vice President, Kaiser Family Foundation), [http://www.aging.senate.gov/imo/media/doc/Neuman\\_3\\_5\\_14.pdf](http://www.aging.senate.gov/imo/media/doc/Neuman_3_5_14.pdf) [<https://perma.cc/2NGP-8K4A>]; see also *Visualizing Income and Assets Among Medicare Beneficiaries: Now and In the Future*, KAISER FAM. FOUND. (June 2014), <http://kff.org/interactive/visualizing-income-and-assets-among-medicare-beneficiaries-now-and-in-the-future> [<https://perma.cc/H8VW-XARH>] (noting that, in 2013, fifty-three percent of all Medicare beneficiaries had “less than \$25,000 in income on a per person basis”).

<sup>123</sup> See, e.g., Travis Waldron, *Why the Decline in Pensions Will Mean an Increase in Poverty for America's Retirees*, THINKPROGRESS (Aug. 8, 2012, 2:30 PM), <http://thinkprogress.org/economy/2012/08/08/656681/pension-decline-poverty-increase> [<https://perma.cc/UEB8-JNUE>]; ALICIA H. MUNNELL ET AL., CTR. FOR RET. RESEARCH AT BOSTON COLL., NRRU UPDATE SHOWS HALF STILL FALLING SHORT 5 (Dec. 2014), [http://ctr.bc.edu/wp-content/uploads/2014/12/IB\\_14-20-508.pdf](http://ctr.bc.edu/wp-content/uploads/2014/12/IB_14-20-508.pdf) [<https://perma.cc/3KUJ-CVS4>].

<sup>124</sup> See, e.g., Pamela Yip, *Middle Class Struggles to Preserve Retirement Security*, NEW AM. MEDIA (Nov. 19, 2014), <http://newamericamedia.org/2014/11/middle-class-struggles-to-preserve-retirement-security.php> [<https://perma.cc/8MVF-U3A8>].

<sup>125</sup> See *id.*

their homes and fewer overall assets.<sup>126</sup> Many experts project that poverty rates among seniors will continue to rise in the foreseeable future, with one source anticipating a 180% increase in the number of seniors living in poverty by the year 2050.<sup>127</sup>

Additionally, the costs of medical care have skyrocketed in the last fifty years.<sup>128</sup> When originally enacted, Medicare was designed to cover hospital costs and limited physician and other health services. While there was a concern at that time that individual seniors were unable to pay their hospital bills, overall health costs were not a concern.<sup>129</sup> It was only later that health care costs began their rapid ascent.<sup>130</sup> By 2009, health care costs had increased from one percent of the Gross Domestic Product (“GDP”) in 1960 to more than seven percent.<sup>131</sup>

Another cause of senior poverty is the increased health care spending that accompanies aging.<sup>132</sup> Health care expenses account for fifteen percent of a Medicare household budget,<sup>133</sup> an amount three times greater than non-Medicare households spend on health care.<sup>134</sup> While Medicare spending per

<sup>126</sup> See, e.g., *id.* (quoting Eric Kingson, co-director of Social Security Works and professor at Syracuse University’s Aging Studies Institute).

<sup>127</sup> Teresa Ghilarducci, *By 2050, There Could Be as Many as 25 Million Poor Elderly Americans*, ATLANTIC (Dec. 30, 2015), <http://www.theatlantic.com/business/archive/2015/12/elderly-poverty-america/422235> [<https://perma.cc/FK86-ADTQ>]. While a large part of this increase is due to the growing number of seniors, approximately one-third relates to a weakening retirement security system. *Id.*; see also Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries, 2014–2030*, KAISER FAM. FOUND. (Sept. 10, 2015), <http://kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2014-2030> [<https://perma.cc/26EV-2UXJ>].

<sup>128</sup> See, e.g., *Health Costs: A Primer*, KAISER FAM. FOUND. (May 1, 2012), <http://kff.org/report-section/health-care-costs-a-primer-2012-report> [<https://perma.cc/NPF3-W3JQ>] (noting that health care costs have increased from an average of \$356 per person in 1970 to \$8,402 per person in 2010). Health care spending increased over the last fifty years by 1.1–3.0% more than the rest of the economy, although that trend has slowed somewhat in the last decade. *Id.*

<sup>129</sup> See *infra* text accompanying notes 220–225.

<sup>130</sup> See, e.g., *Health Costs: A Primer*, *supra* note 128.

<sup>131</sup> Christopher Chantrill, *U.S. Health Care Spending History from 1900*, USGOVERNMENTSPENDING.COM, [http://www.usgovernmentspending.com/healthcare\\_spending](http://www.usgovernmentspending.com/healthcare_spending) [<https://perma.cc/3K54-B2WW>] (noting this trend, which showed health care spending as a portion of the Gross Domestic Product rising from 1% in 1960, to 2% in 1970, 3% in 1980, 5.3% in 1995, and 7% in 2009); see also Dana P. Goldman & Abby E. Alpert, *Costs and Insurance*, in DANA P. GOLDMAN & ELIZABETH A. MCGLYNN, *U.S. HEALTH CARE: FACTS ABOUT COSTS, ACCESS AND QUALITY* 1, 3 (2005), [http://www.rand.org/content/dam/rand/pubs/corporate\\_pubs/2005/RAND\\_CP484.1.pdf](http://www.rand.org/content/dam/rand/pubs/corporate_pubs/2005/RAND_CP484.1.pdf) [<https://perma.cc/W4FG-68CT>] (noting an increase in real health care spending in the United States from five percent of the GDP in 1960 to fifteen percent in 2002).

<sup>132</sup> See, e.g., Juliette Cubanski et al., *Health Care on a Budget: The Financial Burden of Health Spending by Medicare Households*, KAISER FAM. FOUND. (Jan. 9, 2014), <http://kff.org/medicare/issue-brief/health-care-on-a-budget-the-financial-burden-of-health-spending-by-medicare-households> [<https://perma.cc/CAF9-RSZE>].

<sup>133</sup> KAREN DAVIS ET AL., THE COMMONWEALTH FUND, *MEDICARE: 50 YEARS OF ENSURING COVERAGE AND CARE* 7 (Apr. 2015), [http://www.commonwealthfund.org/~media/files/publications/fund-report/2015/apr/1812\\_davis\\_medicare\\_50\\_years\\_coverage\\_care.pdf](http://www.commonwealthfund.org/~media/files/publications/fund-report/2015/apr/1812_davis_medicare_50_years_coverage_care.pdf) [<https://perma.cc/2YQY-UZLU>].

<sup>134</sup> See *id.*

beneficiary is expected to continue to rise, there is reason to believe that the growth rate may be slowing.<sup>135</sup>

Although a disproportionate number of people relying on Medicare are low-income, many are not poor enough to qualify for Medicaid. In 2014, half of all Medicare beneficiaries had incomes below \$24,150, with one quarter having incomes below \$14,350.<sup>136</sup> In 2010, eighteen percent of Medicare beneficiaries had no supplemental coverage to compensate for Medicare's limited coverage options.<sup>137</sup> This group included a disproportionate share of those with incomes between \$10,000 and \$20,000, those living in rural communities, and African American beneficiaries.<sup>138</sup> Substantial disparities in income, savings, and home equity exist among Medicare beneficiaries depending on race and ethnicity.<sup>139</sup> In 2012, the median income, savings, and amount of home equity were substantially lower for black and Hispanic Medicare beneficiaries than white beneficiaries.<sup>140</sup> Twenty percent of black and Hispanic beneficiaries had no savings or were in debt.<sup>141</sup> Today, the cost of a hearing aid is beyond the reach of many seniors, and this burden of inadequate insurance coverage falls disproportionately on people of color.

Given the limited insurance coverage and the poverty facing seniors, an out-of-pocket expenditure of \$2,000 to \$7,000 is simply not feasible. A small number of options other than insurance exist for seniors with presbycusis. For example, eligible veterans may obtain hearing devices for free.<sup>142</sup> And there are a limited number of programs that provide financial assistance for the general public.<sup>143</sup> However, those options neither meet the need for nor compensate for the shortage of available insurance coverage.

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<sup>135</sup> MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 4 (Mar. 14, 2014), [http://medpac.gov/documents/reports/mar14\\_entirereport.pdf](http://medpac.gov/documents/reports/mar14_entirereport.pdf) [<https://perma.cc/MC3C-CFVV>] ("Medicare spending per beneficiary over the next 10 years is projected to grow at a slower rate than in the past 10 years (3.3 percent annually compared with 6.1 percent annually).").

<sup>136</sup> Jacobson et al., *supra* note 127.

<sup>137</sup> *Medicare at a Glance*, *supra* note 94.

<sup>138</sup> *Id.*

<sup>139</sup> See Jacobson et al., *supra* note 103.

<sup>140</sup> *See id.*

<sup>141</sup> *Id.*

<sup>142</sup> For a list of those categories of veterans eligible for hearing aids, see *Federal Benefits for Veterans, Dependents and Survivors, Chapter 1 Healthcare Benefits*, U.S. DEP'T VETERANS AFF., [http://www.va.gov/opa/publications/benefits\\_book/benefits\\_chap01.asp](http://www.va.gov/opa/publications/benefits_book/benefits_chap01.asp) [<https://perma.cc/CH2X-EWDP>]. If eligible, the veteran receives the services and hearing aid free of charge. *Id.*

<sup>143</sup> See, e.g., *Financial Assistance: Programs & Foundations*, HEARING LOSS ASS'N AMERICA, <http://hearingloss.org/content/financial-assistance-programs-foundations> [<https://perma.cc/T5XW-ELRV>]. For those who use PSAPs as an alternative, they spend on average \$250–\$350 for a device. Gandel, *supra* note 75.

IV. THE RELATIONSHIP BETWEEN PRESBYCUSIS  
AND OTHER MEDICAL CONDITIONS

The scientific literature is replete with evidence of the relationship between age-related hearing loss and other medical conditions. For example, recent research indicates a link between hearing loss and dementia, with a leading study concluding that hearing loss is independently associated with dementia.<sup>144</sup> The study consisted of participants between the ages of thirty-six and ninety who had audiometric testing done and also were dementia free.<sup>145</sup> The participants were followed for a median of 11.9 years, and the risk of dementia was found to increase with the severity of the baseline hearing loss.<sup>146</sup> Other studies have reached similar results, concluding that participants with Alzheimer's-type dementia had a higher degree of hearing loss than those in the control group.<sup>147</sup> This study also concluded that greater hearing loss is associated with higher adjusted relative odds of having dementia.<sup>148</sup>

Although the precise cause of this connection between dementia and hearing is unclear, two hypotheses exist. The “effortful hypothesis” posits that those with hearing loss must contribute extra cognitive resources to hearing, and therefore have fewer resources available for other cognitive functions.<sup>149</sup> The second hypothesis suggests that the other consequences of hearing loss—such as reduced social engagement, isolation, and depression—diminish an individual's ability to participate in the very type of activities likely to decrease the risk of dementia.<sup>150</sup> The only real doubt, according to one leading researcher in the field, Johns Hopkins School of Medicine

<sup>144</sup> Lin et al., *supra* note 7, at 217–18; *see also* Stig Arlinger, *Negative Consequences of Uncorrected Hearing Loss—A Review*, 42 INT'L J. AUDIOLOGY 2S17, 2S17 (2003) (noting that hearing loss “is clearly related to depression and dementia”).

<sup>145</sup> Lin et al., *supra* note 7, at 214.

<sup>146</sup> *Id.*

<sup>147</sup> Richard F. Uhlmann et al., *Relationship of Hearing Impairment to Dementia and Cognitive Dysfunction in Older Adults*, 261 JAMA 1916, 1916–19 (1989).

<sup>148</sup> *Id.*; *see* Arlinger, *supra* note 144, at 2S20. For a contrary conclusion from a dated study, *see* Virginia Gennis et al., *Hearing and Cognition in the Elderly: New Findings and a Review of the Literature*, 151 ARCHIVES INTERNAL MED. 2259, 2259–64 (1991) (concluding that there is no meaningful association between hearing loss and later cognitive function).

<sup>149</sup> Lin et al., *supra* note 8, at 770; *see also* Luigi Ferrucci, *Functional Reserves and Hearing*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 21, 21 (2014), <http://www.nap.edu/read/18735/chapter/4#21> [<https://perma.cc/5CL2-KPKK>] (noting that when people have trouble hearing, they have to expend more resources trying to hear; dual tasks create a competition for brain resources; and seniors often have fewer functional reserves to draw upon to assist with a sensory loss such as hearing loss). *See generally* Jonathan E. Peele et al., *Hearing Loss in Older Adults Affects Neural Systems Supporting Speech Comprehension*, 31(35) J. NEUROSCIENCE 12,638 (2011) (illustrating that observed behavior in neural activity suggests that sensory changes have cascading consequences for other neural processes). This view is consistent with seniors' subjective reports that the constant effort to understand speech when their hearing is diminished results in mental fatigue. *See, e.g.*, Tun et al., *supra* note 2, at 765.

<sup>150</sup> *See* Lin et al., *supra* note 7, at 218.

Professor Frank Lin, is the precise mechanism that causes the link between dementia and hearing loss.<sup>151</sup> Additional research confirming these results could have substantial implications for the treatment of individuals with hearing loss and public health issues more broadly.<sup>152</sup>

Early intervention and effective treatment can reduce the impact of hearing loss and thus reduce the prevalence of hearing loss-related diseases.<sup>153</sup> These diseases, such as dementia, have enormous social and economic costs.<sup>154</sup> For example, it is estimated that dementia affects approximately 5.3 million people in the United States,<sup>155</sup> with the direct cost of care in 2010 at \$157–215 billion annually.<sup>156</sup> Costs are estimated to rise to over \$1.1 trillion by 2050.<sup>157</sup> Given this dynamic, insurance coverage for screenings and hearing aids for the elderly may help prevent or delay the onset of dementia and lower its social and economic costs.

Dementia is only one such medical problem related to untreated presbycusis. Presbycusis also may result in poorer cognitive functioning more generally.<sup>158</sup> For example, empirical research has demonstrated a link between recall and hearing loss.<sup>159</sup> In one study, seniors experiencing relatively minor hearing loss were found to have a reduced ability to recall words than those without hearing loss.<sup>160</sup> A subsequent study demonstrated that older adults with greater hearing loss performed worse on tests measuring memory and

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* at 219.

<sup>153</sup> *Id.* at 220.

<sup>154</sup> See, e.g., 2015 *Alzheimer's Disease Facts and Figures*, ALZHEIMER'S ASS'N, [https://www.alz.org/alzheimers\\_disease\\_facts\\_and\\_figures.asp#prevalence](https://www.alz.org/alzheimers_disease_facts_and_figures.asp#prevalence) [<https://perma.cc/ZQN4-YKFE>]; see also Michael D. Hurd et al., *Monetary Costs of Dementia in the United States*, 368(14) *NEW ENG. J. MED.* 1326, 1326 (2013).

<sup>155</sup> See *Alzheimer's Disease Facts and Figures*, *supra* note 154.

<sup>156</sup> See Hurd et al., *supra* note 154, at 1326.

<sup>157</sup> See *Alzheimer's Disease Facts and Figures*, *supra* note 154.

<sup>158</sup> See Lin et al., *supra* note 12, at 294; Tun et al., *supra* note 2, at 764–65; see also Sushmit Mishra et al., *Cognitive Spare Capacity in Older Adults with Hearing Loss*, 6(96) *FRONTIERS AGING NEUROSCIENCE* 1, 11 (2014), <http://journal.frontiersin.org/article/10.3389/fnagi.2014.00096/abstract> [<https://perma.cc/URU6-ASYU>] (concluding that “[o]lder adults with hearing loss have lower CSC (cognitive spare capacity) than young adults without hearing loss, probably because they have poorer cognitive skills and deploy them differently”); Jerker Rönnerberg et al., *Hearing Loss Is Negatively Related to Episodic and Semantic Long-Term Memory but Not to Short-Term Memory*, 54 *J. SPEECH, LANGUAGE, & HEARING RES.* 705–26 (2011) (finding “hearing loss was selectively and negatively related to episodic and semantic long-term memory”); Rachel V. Wayne & Ingrid S. Johnsrude, *A Review of Causal Mechanisms Underlying the Link Between Age-Related Hearing Loss and Cognitive Decline*, 23 *AGEING RES. REVS.* 154, 154–166 (2015) (concluding that as the elderly experience hearing loss, speech perception makes greater demands on cognition, with increased demands unmasking potential cognitive decline).

<sup>159</sup> Tun et al., *supra* note 2, at 761–66.

<sup>160</sup> *Id.* at 765–66. This finding supports the theory that a sensory deprivation such as hearing loss requires extra effort, which results in attentional resources being diverted from other cognitive tasks. *Id.*

executive function.<sup>161</sup> Again, although the precise link between hearing loss and decreased cognitive functioning is unclear,<sup>162</sup> any finding that hearing loss and cognitive decline are related renders it imperative to treat the hearing loss.

Untreated hearing loss can result in a lower quality of life.<sup>163</sup> In a test measuring functional health and well-being, those with a self-reported hearing handicap and severe hearing loss reported lower scores on several domains.<sup>164</sup> Additional negative consequences included activity limitations, increasing reliance on family and other social supports, and negative well-being.<sup>165</sup> Hearing loss also causes isolation, as those who cannot hear well tend to avoid social situations where they cannot hear or may need to hear.<sup>166</sup> This isolation in turn leads to increased loneliness and depression.<sup>167</sup>

Additionally, hearing loss may result in an increased risk of falling,<sup>168</sup> which creates a potential cascade of other medical problems. People experiencing untreated hearing loss spend more days hospitalized than those without hearing loss.<sup>169</sup> One study indicated that those with moderate to severe hearing impairments had significantly poorer driving records when faced with auditory distractions, and those with hearing loss were more likely to have ceased driving, resulting in a loss of independence.<sup>170</sup>

While the precise impact of adequate treatment for presbycusis deserves extensive additional research,<sup>171</sup> hearing aid interventions can alleviate depressive symptoms, reduce social isolation, and improve quality of life

<sup>161</sup> Lin et al., *supra* note 8, at 763–64. In contrast, elderly patients who received cochlear implants were found to have improved cognitive abilities and enhanced quality of life. Mosnier et al., *supra* note 67, at 442–50.

<sup>162</sup> Arlinger, *supra* note 144, at 2S20; Lin et al., *supra* note 7, at 217–20; Lin et al., *supra* note 8, at 763–70.

<sup>163</sup> See, e.g., Gopinath et al., *supra* note 9, at 150; Lopez et al., *supra* note 2, at 363.

<sup>164</sup> Barbara E. Weinstein, *Psychosocial Impacts*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 25, 27 (2014), <http://www.nap.edu/read/18735/chapter/4#27> [<https://perma.cc/8TP2-BRHH>] (citing Dayna S. Dalton et al., *The Impact of Hearing Loss on Quality of Life in Older Adults*, 43(5) GERONTOLOGIST 661, 661–68 (2003)). The severity and type of hearing loss affected self-reported measures of well-being. Weinstein, *supra* note 164, at 27.

<sup>165</sup> Gopinath et al., *supra* note 9, at 146.

<sup>166</sup> Arlinger, *supra* note 144, at 2S17–2S18.

<sup>167</sup> *Id.*

<sup>168</sup> Lopez et al., *supra* note 2, at 359; see also Anne Viljanen et al., *Hearing as a Predictor of Falls and Postural Balance in Older Female Twins*, 64A J. GERONTOLOGY SERIES A: BIOLOGICAL MED. SCI. 312, 312 (2009).

<sup>169</sup> Dane J. Genther et al., *Association of Hearing Loss with Hospitalization and Burden of Disease in Older Adults*, 309(22) JAMA 2322, 2323 (2013).

<sup>170</sup> Alan M. Jette, *The Impact of Hearing Loss on Physical Functioning*, in INST. OF MED. & NAT'L RESEARCH COUNCIL, HEARING LOSS & HEALTHY AGING: WORKSHOP SUMMARY 19, 20 (2014), <http://www.nap.edu/read/18735/chapter/4#18> [<https://perma.cc/3AGC-HWCF>].

<sup>171</sup> See Lin et al., *supra* note 7, at 219 (stating that whether hearing devices and rehabilitation strategies could have an effect on cognitive decline and dementia is unknown and requires further research).

for seniors with hearing loss.<sup>172</sup> Hearing aid users show significant improvement in both mental<sup>173</sup> and physical domain<sup>174</sup> tests, and show a smaller decline in vitality than those who do not use hearing aids.<sup>175</sup> Researchers hypothesize that the use of hearing aids promotes “feelings of being competent, confident, and inclined (or motivated) to exploit life’s possibilities . . . and could thus improve overall well-being.”<sup>176</sup> Addressing hearing loss, through both “preventive strategies focusing on timely identification of persons with hearing handicap, as well as . . . referral to hearing services could both counteract the poor use of prescribed hearing aids and preserve [quality of life] in older hearing-impaired adults.”<sup>177</sup>

These connections between hearing loss and various medical and social conditions form a sufficient basis for providing insurance coverage for all screenings—even for those who are asymptomatic<sup>178</sup>—and for hearing aids. While more research on these issues would be helpful, the quality of life for many seniors hangs in the balance. Additional insurance coverage cannot wait until these connections are thoroughly explained.

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<sup>172</sup> Gopinath et al., *supra* note 9, at 146–51. These findings come from a study of approximately 850 participants with hearing loss who were evaluated over a fifteen-year period. *Id.* at 147. Participants responded to the “36-Item Short-Form Survey (SF-36)” which measures the following characteristics: “‘physical functioning’, ‘role limitations due to physical problems’, ‘bodily pain’, ‘general health perceptions’, ‘vitality’, ‘social functioning’, ‘role limitations due to emotional problems’, and ‘mental health’.” *Id.* Those who used hearing aids demonstrated higher scores in the “mental composite” score and in the “mental health” domain compared to non-hearing aid users. *Id.* at 148. Additionally, those with self-perceived hearing loss experienced a larger negative impact on quality of life than those with measured but uncorrected hearing loss. *Id.*; see also Arlinger, *supra* note 144, at 2S19 (citing Francesco Cacciatore et al., *Quality of Life Determinants and Hearing Function in an Elderly Population: Osservatorio Geriatrico Campano Study Group*, 45 GERONTOLOGY 323 (1999)); Chisolm, *supra* note 50, at 33–34 (citing Cynthia D. Mulrow et al., *Association Between Hearing Impairment and the Quality of Life of Elderly Individuals*, 38(1) J. AM. GERIATRICS SOC’Y 45 (1990)); Adrian Davis et al., *Acceptability, Benefits, and Costs of Early Screening for Hearing Disability: A Study of Potential Screening Tests and Models*, 11(42) HEALTH TECH. ASSESSMENT 1, 1 (2007); Chuan-Fen Liu et al., *Long-term Cost-effectiveness of Screening Strategies for Hearing Loss*, 48 J. REHABILITATION RES. & DEV. 235, 235 (2011); Cynthia D. Mulrow et al., *Quality-of-life Changes and Hearing Impairment*, 113 ANNALS OF INTERNAL MED. 188, 188 (1990). *But cf.* Cynthia D. Mulrow et al., *Sustained Benefits of Hearing Aids*, 35 J. OF SPEECH, LANGUAGE, & HEARING RES. 1402, 1402 (1992) (finding cognitive changes reverted back to baseline after twelve months).

<sup>173</sup> Gopinath et al., *supra* note 9, at 146–51.

<sup>174</sup> Weinstein, *supra* note 164, at 27 (citing E. M. Chia et al., *Hearing Impairment and Health-Related Quality of Life: The Blue Mountains Hearing Study*, 28(2) EAR & HEARING 187, 187–95 (2007)).

<sup>175</sup> Gopinath et al., *supra* note 9, at 148. Experts agree that more research is needed as to the efficacy of hearing aids and other communication strategies in improving health. See, e.g., Weinstein, *supra* note 164, at 28.

<sup>176</sup> Gopinath et al., *supra* note 9, at 150.

<sup>177</sup> *Id.*

<sup>178</sup> For a discussion of the United States Prevention Services Task Force (“USPSTF”) and its withdrawal of its earlier recommendation for asymptomatic screening, see *infra* notes 246–252 and accompanying text.

## V. LEGAL ARGUMENTS FOR ENHANCED INSURANCE COVERAGE OF HEARING AIDS

The ACA represents a dramatic shift from the perspective of the 1965 Medicare statute, which was designed to cover the increasing health care costs that accompany old age and, in particular, the costs of a severe illness.<sup>179</sup> In contrast, the ACA reflects a largely preventive focus, transforming “the U.S.’s public and private health care financing systems into vehicles for promoting public health.”<sup>180</sup> The ACA includes opportunities and funding for innovations to enhance quality of care and reduce costs within the Medicare and Medicaid programs, provisions requiring a plethora of preventive services, all mandated at no cost, and the more well-known provisions requiring health insurance for all Americans. While the ACA does not override Medicare’s statutory exclusion of hearing aid coverage, it does build on a gradual transformation of Medicare from a program providing coverage largely for expensive medical care to one promoting health and broad coverage of routine but necessary medical services.<sup>181</sup> One author describes the ACA’s expansion of Medicare coverage to preventive care and care management as “manifest[ing] a recognition that the traditional Medicare benefits and coverage package . . . [does] not permit the Medicare program to cover the range of health-related services that are warranted based upon the needs of Medicare beneficiaries, sound medical practices, and information developed by medical and other sciences.”<sup>182</sup> The changes in the Medicare law since its enactment as well as the ultimate passage of the ACA conflict with Medicare’s 1965 statutory exclusion of hearing aids. They also highlight a philosophical divide between the two major health care initiatives of the last sixty years. The ACA reflects contemporary thinking on the role of health insurance, and it can be utilized to amend the Medicare law and ultimately mandate insurance coverage of hearing devices.

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<sup>179</sup> See, e.g., *History of SSA During the Johnson Administration 1963-1968*, SOC. SECURITY ADMIN., <https://www.ssa.gov/history/ssa/lbjmedicare1.html> [<https://perma.cc/R6PS-7QUC>] (noting that, in 1965, slightly over half of all seniors had any insurance coverage for hospitalization and even those with substantial savings “faced the threat of being wiped out financially by a severe illness”). One history of Medicare states that when John F. Kennedy and Richard Nixon discussed health care coverage, “Health insurance . . . was synonymous with hospital insurance.” WILLIAM A. PEARMAN & PHILIP STARR, *MEDICARE: A HANDBOOK ON THE HISTORY AND ISSUES OF HEALTH CARE SERVICES FOR THE ELDERLY* 7 (1988).

<sup>180</sup> John Aloysius Cogan, Jr., *The Affordable Care Act’s Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J.L. MED. & ETHICS 355, 355 (2011). For further discussion of a public health perspective on hearing services, see Burkard, *supra* note 88, at 76–77.

<sup>181</sup> For a discussion of the gradual evolution within Medicare, see generally DeBoer, *supra* note 16; Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program*, 13 YALE J. HEALTH POL’Y, L. & ETHICS 253, 258 (2013) (describing the ACA reforms with respect to Medicare as “simply steps in the implementation of reforms already in place”).

<sup>182</sup> DeBoer, *supra* note 16, at 495–96.

This Part will begin by outlining the preventive care focus of the ACA. It will then describe Medicare, given its role as the primary insurer of seniors, providing a summary of the history and purpose of the legislation, particularly as it relates to hearing aids. This Part recommends avenues for enhancing coverage of these devices for Medicare beneficiaries in light of the ACA. These avenues include recommending that the Secretary, as permitted under the ACA, authorize pilot projects providing insurance coverage of hearing devices in the Medicare program. This Part also highlights specific ACA provisions that, but for the Medicare statutory exclusion, could be construed to provide insurance coverage of hearing devices, and demonstrate that these provisions justify amending Medicare to provide such coverage. In its final section, this Part proposes methods of expanding coverage of hearing aids under the Medicaid program and private insurance plans.

### A. Preventive Care Focus of the ACA

The ACA reflects a focus on and is replete with preventive care coverage requirements. The statute provides for two sets of specific covered preventive services. First, the ACA requires a wide range of preventive services for all insured people, including alcohol counseling, vaccinations, and screenings for depression, HIV, Type 2 diabetes, obesity, and tobacco use.<sup>183</sup> Secondly, the ACA requires specific screenings for select populations,<sup>184</sup> and mandates preventive screening and other services for the elderly through the Medicare program.<sup>185</sup> Specific preventive services for seniors include bone mass measurements, cardiovascular disease screening, medical nutrition therapy, prostate cancer screening, glaucoma tests, and flu shots, among others.<sup>186</sup> Under the ACA, Medicare recipients receive these services in the ACA-mandated initial “Welcome to Medicare” visit, annual “wellness visits,” and personalized prevention plans.<sup>187</sup> Additionally, the Secretary of the

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<sup>183</sup> See 42 U.S.C. § 300gg-13 (a) (1) (2012); *Preventive Services Covered Under the Affordable Care Act*, U.S. DEPT OF HEALTH & HUMAN SERVS. (Sept. 23, 2010), <http://www.hhs.gov/healthcare/facts/factsheets/2010/07/preventive-services-list.html> [<https://perma.cc/BB8B-3GEH>].

<sup>184</sup> See *What Free Screenings Does the ACA Require?*, AM. MED. NEWS (Aug. 2013), <http://m.amednews.com/article/20130812/government/130809971&template=mobileart> [<https://perma.cc/XYU9-MLP6>].

<sup>185</sup> *The Affordable Care Act and Older Americans*, U.S. DEPT OF HEALTH & HUMAN SERVS. (Mar. 19, 2015), <http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/aca-and-older-americans/index.html> [<https://perma.cc/XBK6-433A>]. For a list of all preventive services available to Medicare recipients, see *Preventive Services*, CTRES. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/PreventiveServicesPoster.pdf> [<https://perma.cc/FZQ8-F3MJ>].

<sup>186</sup> *The Affordable Care Act and Older Americans*, *supra* note 185. For further discussion of the expansive nature of these preventive services for seniors, see DeBoer, *supra* note 16, at 537–40.

<sup>187</sup> DeBoer, *supra* note 16, at 537 (citing Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 4103(b), 124 Stat. 119, 553–55 (2010) (codified as amended at

Department of Health and Human Services (“HHS”) is authorized to modify the list of “no-cost” preventive services if the modification is consistent with United States Preventive Services Task Force (“USPSTF”) recommendations and with services required in the initial prevention visit.<sup>188</sup> These mandated preventive services must be provided at no cost to the patient, including no copays and no deductibles.<sup>189</sup> A radical departure from prior law and policy, this “no-cost” requirement applies to Medicare recipients<sup>190</sup> and to all private health plans, including individual, small group, large group, and self-insured plans, except those plans “grandfathered” under the ACA.<sup>191</sup>

The ACA also requires health insurance plans to include “Essential Health Benefits” (“EHB”), a term defined to include services in ten broad statutory categories.<sup>192</sup> All plans offered in the individual and small group market (as well as Medicaid<sup>193</sup>) are required to provide an EHB package.<sup>194</sup>

42 U.S.C.A. § 1395x(hhh)(4)(G) (West 2015)). Significantly, the ACA specifically provides that its preventive services mandate does not alter coverage of diagnostic or treatment services as outlined in the Medicare program statute. DeBoer, *supra* note 16, at 540 (citing Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 4105(b), 124 Stat. 119, 559 (2010) (“Nothing in the amendment . . . shall be construed to affect the coverage of diagnostic or treatment services under title XVIII of the Social Security Act.”)).

<sup>188</sup> 42 U.S.C.A. § 1395m(n) (West 2015).

<sup>189</sup> 42 U.S.C. § 300gg-13(a)(1) (2012). For further discussion of specific issues arising in the preventive care coverage context, see *Preventive Services Covered by Private Health Plans under the Affordable Care Act*, KAISER FAM. FOUND. (Aug. 4, 2015), <http://kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/> [<https://perma.cc/8M9S-QRZN>].

<sup>190</sup> For a list of Medicare Part B preventive services covered, see *Preventive & Screening Services*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 5, 2012), <http://www.medicare.gov/coverage/preventive-and-screening-services.html> [<https://perma.cc/LB83-CZ8V>]. For information on who is covered by Medicare Part B, see Cubanski et al., *supra* note 4 (citing *March 2015 Medicare Baseline*, CONG. BUDGET OFF. (Mar. 2015), <http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf> [<https://perma.cc/9TTP-XDJU>]). Although regulations governing Medicare Advantage Plans (Part C) are slightly different, those plans, too, are required to provide preventive services at no costs. *Your Medicare Coverage Choices*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/your-medicare-coverage-choices.html> [<https://perma.cc/WWF7-D9Q9>]. A 2012 report from CMS indicates that all Medicare Advantage insurers provided all of the preventive services to their enrollees without cost. See CTRS. FOR MEDICARE & MEDICAID SERVS., *THE AFFORDABLE CARE ACT: A STRONGER MEDICARE PROGRAM* 8 (Feb. 2013), <https://www.cms.gov/apps/files/medicarereport2012.pdf> [<https://perma.cc/2S7G-99EK>].

<sup>191</sup> For a list of Medicare Part B preventive services covered, see *Preventive & Screening Services*, *supra* note 190. For facts on who is covered by Medicare Part B, see Cubanski et al., *supra* note 4 (citing *March 2015 Medicare Baseline*, CONG. BUDGET OFF. (Mar. 2015), <http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf> [<https://perma.cc/9TTP-XDJU>]).

<sup>192</sup> *Essential Health Benefits Standards: Ensuring Quality, Affordable Coverage*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 2, 2013), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ehb-2-20-2013.html> [<https://perma.cc/W9LM-BCRX>].

<sup>193</sup> Plans provided in the Medicaid programs, which are required to offer the same benefits as those contained in an EHB package, are referred to as Alternative Benefit Plans. *Alternative Benefit Plan Coverage*, MEDICAID, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html> [<https://perma.cc/YH59-24PY>]; *Essential Health Benefits Standards: Ensuring Quality, Affordable Coverage*, *supra* note 192.

EHB includes, for example, services related to mental health and substance abuse, maternity and newborn care, emergency services, pediatric services, laboratory services, and rehabilitative and habilitative services.<sup>195</sup> Plans must provide a predetermined level of coverage and require no deductibles, copays, or co-insurance.<sup>196</sup> Although this mandate currently does not apply to large employer plans,<sup>197</sup> large employers are required to limit cost sharing for essential benefits that would otherwise be included in an EHB package.<sup>198</sup>

This shift to a prevention model is evident throughout the ACA. For example, the statute required the establishment of a National Prevention, Health Promotion and Public Health Council (“Council”) within the HHS to “coordinate and lead the federal effort in prevention, wellness, and health promotion practices, the public health system, and integrative health care.”<sup>199</sup> The Act also requires the President to establish an Advisory Group on Prevention, Health Promotion and Integrative and Public Health to advise the Council on “lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion.”<sup>200</sup>

Other prevention-oriented initiatives in the ACA include the creation of both a health education and public outreach campaign and a media campaign focused on health promotion and disease prevention, as well as the develop-

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For specifics on the application of the EHB requirement to the Medicaid context, see, for example, Letter from Cindy Mann, Dir., Ctr. for Medicaid & CHIP Servs., to State Medicaid Dirs. (Nov. 20, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf> [<https://perma.cc/9ZAP-28PP>].

<sup>194</sup> *Essential Health Benefits Standards: Ensuring Quality, Affordable Coverage*, *supra* note 192.

<sup>195</sup> *Id.*

<sup>196</sup> *Preventive Services Covered by Private Health Plans under the Affordable Care Act*, *supra* note 189; see also *Summary of the Affordable Care Act*, KAISER FAM. FOUND. (Apr. 25, 2013), <http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/> [<https://perma.cc/AJ4A-3Q38>].

<sup>197</sup> This was based on the assumption that most large group plans already included these benefits. For further discussion of these issues, see, for example, Christopher Condeluci, *How the ACA Insurance Market Reforms Could Affect Large Employers*, FORBES (Oct. 24, 2014, 5:53 PM), <http://www.forbes.com/sites/realspin/2014/10/24/how-aca-insurance-market-reforms-could-affect-large-employers/> [<https://perma.cc/SQD2-JVE6>].

<sup>198</sup> See generally CTRS. FOR MEDICARE & MEDICAID SERVS. FREQUENTLY ASKED QUESTIONS ON ESSENTIAL HEALTH BENEFITS BULLETIN, <https://www.cms.gov/ccio/resources/files/downloads/ehb-faq-508.pdf> [<https://perma.cc/V6YS-9Y89>]; Condeluci, *supra* note 197.

<sup>199</sup> DeBoer, *supra* note 16, at 535 (citing Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, §§ 4001(a), (d)(1), 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (codified as amended at 26 U.S.C. § 4001 (repealed 2014))).

<sup>200</sup> *Id.* at 534 (citing Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, §§ 4001(f)(1), (3), 124 Stat. 119). This entity is composed of non-federal licensed health professionals. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 4001(f)(2), 124 Stat. 119, 539–40 (codified as amended at 42 U.S.C.A. § 300u-10 (West 2014)).

ment of a website to provide personalized prevention plan tools.<sup>201</sup> The ACA also created a Prevention and Public Health Fund to promote wellness, prevention, and public health activities.<sup>202</sup> It requires the Center for Disease Control and Prevention's Community Prevention Services Task Force to coordinate with the USPSTF to review evidence related to "effectiveness, appropriateness, and cost effectiveness of community prevention interventions."<sup>203</sup> Further, the ACA provides grants for community-based preventive health programs and interventions for seniors.<sup>204</sup> One final example is the establishment of the Patient-Centered Outcomes Research Institute ("PCORI"), an independent body dedicated to evaluating and disseminating information about clinical effectiveness research.<sup>205</sup>

A particularly important provision within the ACA signifies the United States' shifting perspective on health care and health care financing. The ACA created the Center for Medicare and Medicaid Innovation ("Innovation Center") within the Centers for Medicare and Medicaid ("CMS") to test new models for the provision of, and payment for, health care within the Medicare and Medicaid programs.<sup>206</sup> The "twin goals" of these innovations are "enhancing the quality of health and health care while reducing costs through improvement of health outcomes."<sup>207</sup> Significantly, the Secretary is permitted, "solely for the purposes of testing innovative service delivery and payment models, to waive requirements in the Medicare program statute 'as may be necessary.'"<sup>208</sup> This provision paves the way to test the viability of Medicare coverage of hearing aids and would override the statutory hearing aid exclusion.

## B. *The ACA and Medicare Coverage of Hearing Aids*

### 1. *Medicare's Statutory Exclusion*

The Medicare statute explicitly excludes coverage of "routine physical checkups, eyeglasses . . . [and] hearing aids or examina-

<sup>201</sup> *Id.* (citing Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, §§ 4004(a), (c), (e), (f), 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. §§ 300u-12(a), (c), (e), (f) (2012))).

<sup>202</sup> Cogan, *supra* note 180, at 356 (citing 42 U.S.C. § 300u-11 (2012)).

<sup>203</sup> *Id.* (citing 42 U.S.C. § 280(g)-10 (2012)). For recommendations of this Community Prevention Services Task Force, see *All Findings of the Community Preventive Services Task Force, THE COMMUNITY GUIDE* (Dec. 23, 2015), <http://www.thecommunityguide.org/about/conclusionreport.html> [<https://perma.cc/38PT-6PCG>]. Interestingly, none of the Task Force's recommendations relate to hearing health. *Id.* For additional information on the USPSTF, see *infra* notes 245–248.

<sup>204</sup> Cogan, *supra* note 180, at 356 (citing 42 U.S.C. §§ 300u-13–14 (2012)).

<sup>205</sup> 42 U.S.C. § 1320e(b)(1) (2012).

<sup>206</sup> *Center for Medicare and Medicaid Innovation, CTRS. FOR MEDICARE & MEDICAID SERVS.* (Feb. 5, 2016), [https://www.cms.gov/about-cms/agency-information/cmsleadership/office\\_cmmi.html](https://www.cms.gov/about-cms/agency-information/cmsleadership/office_cmmi.html) [<https://perma.cc/D582-E5BD>].

<sup>207</sup> DeBoer, *supra* note 16, at 546.

<sup>208</sup> *Id.* at 549; *see also* 42 U.S.C.A. § 1315a(d)(1) (West 2015).

tions.”<sup>209</sup> While Medicare Part B covers a diagnostic hearing exam if ordered by a physician to determine if medical treatment is necessary, it does not cover routine hearing exams, hearing devices, or exams for the purpose of prescribing, fitting, or changing hearing aids.<sup>210</sup>

Although Medicare’s statutory exclusion of hearing aids conflicts with current health care policy, it was arguably consistent with the goals of the Social Security Act when enacted. Medicare was intended to provide protection against the high costs of hospitalization and medical care<sup>211</sup> and sought to “provide a coordinated approach for health insurance and medical care for the aged under the Social Security Act.”<sup>212</sup> One goal of the program was to help make “economic security in old age more realistic.”<sup>213</sup> Although originally drafted to cover only hospital stays,<sup>214</sup> the legislation was later expanded to cover physician services.<sup>215</sup> After the implementation of the Social Security and Medicare programs, the economic status of elderly Americans improved dramatically.<sup>216</sup> In 1966 seniors paid fifty-six percent of their med-

<sup>209</sup> 42 U.S.C.A. § 1395y(a)(7) (West 2015); *see also* *Zells v. U.S. Sec’y of Health & Human Servs.*, 44 F. App’x 917, 917 (9th Cir. 2011), *cert. denied*, 132 S. Ct. 852 (2011). *Zells* argued that Medicare should cover a hearing aid necessary to compensate for hearing loss due to Medicare-covered treatment for cancer, arguing, *inter alia*, that this was not routine coverage. *Zells*, 44 F. App’x at 917.

<sup>210</sup> *See Your Medicare Coverage*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.medicare.gov/coverage/hearing-and-balance-exam-and-hearing-aids.html> [<https://perma.cc/32QY-A7ZJ>]; CMS PUB. 14 § 15903, HEARING AID EXCLUSION, 2013 WL 3303025. The exclusions in the Medicare statute are implemented through “National Coverage Decisions” (“NCD”), 42 C.F.R. 405.1060 *et seq.* *See also* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html> [<https://perma.cc/UG3R-SJK4>] (describing specific items, services or treatments covered by Medicare). With respect to hearing aids, there have been no coverage decisions, presumably because of the statutory coverage exclusion. The only applicable decision concerns coverage for cochlear implants, which Medicare characterizes as a device “implanted surgically to stimulate auditory nerve fibers.” CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL, CHAPTER 1, at 89–90 (Rev. 187, Dec. 10, 2015), [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part1.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf) [<https://perma.cc/CDY7-8ARJ>]. Coverage is provided for cochlear implants provided the patient qualifies under the standards in the NCD. *Id.* If CMS does not address a given coverage issue through an NCD, a fiscal intermediary or carrier may make a “Local Coverage Decision” (“LCD”) as to whether or not coverage is reasonable and necessary for a particular service or item. *See Medicare Coverage Database*, CTRS. FOR MEDICARE & MEDICAID SERVS., [http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list\\_type=ncd](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd) [<https://perma.cc/C7VU-XAHF>]. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PROGRAM INTEGRITY MANUAL, CHAPTER 13 (Rev. 608, Aug. 14, 2015), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf> [<https://perma.cc/8G8K-AZV6>].

<sup>211</sup> Wilbur J. Cohen & Robert M. Ball, *Social Security Amendments of 1965: Summary and Legislative History*, SOC. SECURITY BULL. 3, 3 (1965).

<sup>212</sup> S. REP. NO. 89-404, at 1943 (1965).

<sup>213</sup> *Id.* at 1964.

<sup>214</sup> *See* Jacqueline Fox, *Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 588 (2005).

<sup>215</sup> *Id.* at 589.

<sup>216</sup> *See, e.g.*, KAREN DAVIS ET AL., MEDICARE: 50 YEARS OF ENSURING COVERAGE AND CARE 10 (2015).

ical expenses out of pocket, while today seniors pay only thirteen percent of their medical expenses out of pocket.<sup>217</sup>

While an earlier, more progressive plan proposed during the Truman administration included coverage for hearing aids and eyeglasses,<sup>218</sup> the original Medicare bill did not cover routine hearing-related services, nor did it cover vision or dental services—including eyeglasses, eye tests, and dental procedures and supplies such as cleanings, fillings, tooth extractions, dentures, and dental plates—or related vision or dental preventive care.<sup>219</sup> Payment was provided for medical services if the patient had a specific complaint, but not “for routine annual or semiannual checkup[s].”<sup>220</sup> There is a dearth of legislative history on these particular statutory exclusions, and the exact reasons for these omissions are lost in history.<sup>221</sup> The exclusions were included despite the legislative goal of making “the best of modern medicine more readily available to the aged.”<sup>222</sup>

One obvious explanation for the exclusion of hearing aids, vision services, and dental care was cost.<sup>223</sup> In analyzing the role of cost in formulating Medicare policy in 1965, Jacqueline Fox writes, “There was no provision made for coverage of preventive care and the premise of Part B, as with Part A, was to be there for cases of emergency and high costs.”<sup>224</sup> Robert M. Ball, Commissioner of Social Security at the time, has explained that the decision not to include coverage for routine care relating to hearing loss and hearing aids was made under the assumption that once seniors gained insurance coverage for the “major costs of hospital and physicians’ services most older people [would] be better able to budget for the costs of routine care . . . .”<sup>225</sup> Ball also has commented that the population likely to benefit

<sup>217</sup> *Id.*

<sup>218</sup> John D. Morris, *Truman’s Health Plan Compared with British*, N.Y. TIMES, May 1, 1949, at E7.

<sup>219</sup> Social Security Act of 1965, Sec. 1862(a)(7), codified at 42 U.S.C. § 1395y(a)(7) (2012); *Dental Services*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.medicare.gov/coverage/dental-services.html> [<https://perma.cc/8725-GSEC>]; see Cohen & Ball, *supra* note 211, at 3.

<sup>220</sup> S. REP. NO. 89-404, at 1990 (1965).

<sup>221</sup> See Lise Hamlin, *Hearing Aid Coverage Under Medicare*, HEARING LOSS MAGAZINE, at 28, 28 (July 1, 2014), [http://www.nxtbook.com/ygsreprints/HLAA/g42663\\_hlaa\\_julau82014/#/28](http://www.nxtbook.com/ygsreprints/HLAA/g42663_hlaa_julau82014/#/28) [<https://perma.cc/PS2F-YFDL>].

<sup>222</sup> S. REP. NO. 89-404, at 1965.

<sup>223</sup> Most scholars assume the exclusion was due to costs. See, e.g., Cassel, *supra* note 36, at 553 (writing that “[t]he justification used in 1965 to exclude hearing aids from Medicare coverage was that hearing technologies were routine and low cost and therefore should be paid for by consumers”); Whitson & Lin, *supra* note 23, at 1740 (“The rationale for noncoverage of sensory aids initially hinged on the notion that consumers should pay for common and affordable items, especially those of limited health benefit.”).

<sup>224</sup> Fox, *supra* note 214, at 589.

<sup>225</sup> *Hearing Loss, Hearing Aids, and the Elderly: Hearing before the Subcomm. on Consumer Interests of the Elderly of the Special Comm. on Aging*, 90th Cong. 309–10 (1968) (statement of Robert M. Ball, Comm’r on Soc. Sec.).

from hearing services was not a “large enough, or strong enough, or savvy enough contingent to be at the table when the bill was drafted.”<sup>226</sup>

Subsequent legislation has attempted to eliminate Medicare’s statutory exclusion of hearing aid coverage. When Medicare expansion was considered in 1968, hearing aid coverage was deemed unlikely because of concerns that new coverage would also have to include eye tests, eyeglasses, and other preventive care.<sup>227</sup> At congressional hearings conducted in 1973, Senator Frank Church described the absence of hearing aid insurance coverage as an issue with “great economic and emotional impact upon the elderly.”<sup>228</sup> He noted that “few disabilities have more harsh impact upon the elderly,” particularly given that hearing loss leads to “emotional isolation.”<sup>229</sup> In 1976, then-Congressman Claude Pepper, Chairman of the Subcommittee on Health and Long Term Care, issued a report that recommended Medicare cover the costs of hearing aids, along with eyeglasses and dentures.<sup>230</sup> As one witness testified, “the use of hearing aids ends the ‘isolation, degradation and loneliness’ of many older people who might otherwise mistakenly be ‘thought to be practically senile.’”<sup>231</sup> Despite this powerful testimony, these efforts failed, as have subsequent attempts to provide such coverage.<sup>232</sup> However, the ACA changes the landscape and evolving medical research alters the dynamic, making this an opportune time to once again advocate for Medicare coverage of hearing aids.<sup>233</sup> Such an amendment would enhance the health of many seniors currently unable to afford hearing aids and is

<sup>226</sup> Hamlin, *supra* note 221, at 28.

<sup>227</sup> *Hearing Loss, Hearing Aids, and the Elderly: Hearing before the Subcomm. on Consumer Interests of the Elderly of the Special Comm. on Aging*, 90th Cong. 309–10 (1968) (statement of Robert M. Ball, Comm’r on Soc. Sec.).

<sup>228</sup> *Hearing Aid and the Older American: Hearings before the Subcomm. on Consumer Interests of the Elderly of the Special Comm. on Aging*, 93rd Cong. 1 (1973) (statement of Sen. Frank Church, Chairman, Special Comm. on Aging).

<sup>229</sup> *Id.* Senator Church noted that even the former Secretary of Health, Education and Welfare, Wilbur Cohen, who opposed Medicare coverage of hearing aids in 1965, believed by 1973 that providing coverage, with a small deductible, was feasible. *See id.*; *see also* INTERDEPARTMENTAL TASK FORCE, DEPT’S OF HEALTH, EDUCATION, & WELFARE, *NEW PERSPECTIVES IN HEALTH CARE FOR OLDER AMERICANS* 52 (1976), <https://ia601700.us.archive.org/7/items/netivesi00unit/netivesi00unit.pdf> [<https://perma.cc/SE3X-PFRY>] (recommending that Medicare Part B cover hearing aids, eyeglasses and dentures).

<sup>230</sup> *See generally* H.R. SUBCOMM. ON HEALTH AND LONG-TERM CARE OF THE SELECT COMM. ON AGING, 94TH CONG., *MEDICAL DEVICES AND THE ELDERLY: UNMET NEEDS AND EXCESSIVE COSTS FOR EYEGLASSES, HEARING AIDS, DENTURES AND OTHER DEVICES* (1976). After noting the expense of hearing devices, the Report also pointed out conflicts of interest in the hearing aid industry, inadequate training of hearing aid dealers, an absence of educational requirements for hearing aid dealers in some states, lack of industry oversight, and overpricing and excessive costs. *See id.* Additional issues within the hearing aid industry, while potentially still relevant today, are beyond the scope of this paper.

<sup>231</sup> *Id.* (citing the testimony of Dr. Blue Carstenson).

<sup>232</sup> *See, e.g.*, Medicare Hearing Enhancement and Auditory Rehabilitation (HEAR) Act of 2007, H.R. 1912, 110th Cong. (2007); Medicare Hearing Enhancement and Auditory Rehabilitation (HEAR) Act of 2009, S. 1837, 111th Cong. (2009). *See infra* notes 262–281 and accompanying text for discussion of legislation currently pending.

<sup>233</sup> For arguments in support of altering Medicare policies, *see, for example*, Whitson & Lin, *supra* note 23, at 1739 (“Given present-day understanding of the health effects of sensory

consistent with the ACA's dual goals of enhancing the quality of care while reducing costs.<sup>234</sup>

## 2. *The ACA and Insurance Coverage of Hearing Aids for Medicare Beneficiaries*

The philosophy embodied in the ACA provides opportunities to expand insurance coverage of hearing aids. The Secretary could, and should, use her authority under the ACA to implement model projects requiring insurance coverage of hearing devices, even for Medicare beneficiaries. Additionally, the statutory requirements of a wide range of preventive services at no cost, some of which arguably should include hearing aids, justifies amending the Medicare statute to provide such coverage. The recent and mounting empirical evidence of additional medical problems caused by, and related to, untreated hearing loss warrants these changes.

### a. *Implement Pilot Projects Authorizing Coverage of Hearing Devices*

The Act authorizes the Secretary to test innovative service delivery and payment models that “focus on the twin goals of improving health care quality and reducing spending.”<sup>235</sup> The previously-mentioned Center for Medicare and Medicaid Innovation (“Innovation Center”), an entity within CMS, is the repository for pilot projects, and currently prioritizes “[t]esting new payment and service delivery models, [e]valuating results and advancing best practices,” and “[e]ngaging a broad range of stakeholders to develop additional models for testing.”<sup>236</sup> All projects are carefully evaluated, examining quality of care, including patient outcomes, and the models’ impact on spending.<sup>237</sup> Participating entities are provided feedback throughout the demonstration, and the Innovation Center promotes “broad and rapid dissemination of evidence and best practices that have the potential to deliver higher

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loss and advances in technology, Medicare policy for coverage of hearing and vision rehabilitative services, established a half century ago, may need reconsideration.”)

<sup>234</sup> Determining the actual costs of providing hearing devices through Medicare is beyond the scope of this article. However, Medicare coverage of hearing aids would potentially minimize the expense of health care costs for medical conditions caused or exacerbated by untreated hearing loss. For a general discussion of this principle, see, for example, Scott Solkoff, *Report on the Patient Protection and Affordable Care Act: Its Impact on the Special Needs and Elder Law Practice*, 11 NAELA J. 1, 18 (2015) (noting that “[b]y emphasizing more proactive health care, it is believed that the overall need for and cost of health care will decrease because the need for treatment will decrease”).

<sup>235</sup> DeBoer, *supra* note 16, at 549 (citing 42 U.S.C.A. § 1315a(a)(1) (West 2015)).

<sup>236</sup> *About the CMS Innovation Center*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/about/index.html> [<https://perma.cc/L2KY-8A83>] (last updated Oct. 21, 2015). For a more specific list of “Model Design Factors,” see *Model Design Factors*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/Files/x/rfi-websit preamble.pdf> [<https://perma.cc/VN3N-MF22>].

<sup>237</sup> *About the CMS Innovation Center*, *supra* note 236.

quality and lower cost care.”<sup>238</sup> Projects must address the needs of Medicare beneficiaries, Medicaid beneficiaries, or those individuals who participate in both programs.<sup>239</sup> Pilot projects currently underway include an “Oncology Care Model,” a “Medicaid Emergency Psychiatric Demonstration” model, and an “Independence at Home” model for Medicare beneficiaries with multiple chronic conditions.<sup>240</sup>

Pilot projects providing coverage of hearing aids in the Medicare program would satisfy the ACA’s goals and CMS’s priorities as well as offer numerous benefits. First, the pilots would enable CMS to evaluate the impact of this coverage on health care quality and patient improvement. Second, they would provide CMS with the data necessary to evaluate the relative costs of providing hearing aid coverage within the Medicare program compared with the costs of addressing the medical, social, and other consequences of untreated presbycusis. Finally, and most importantly, such projects would bypass the current Medicare statutory exclusion of hearing aids on an interim basis, providing insurance coverage of hearing aids for the many seniors who need them both to prevent the attendant health consequences of untreated hearing loss and to maintain their quality of life. Such a project, ideally suited for the Innovation Center, would generate invaluable data and insights to broadly inform insurance coverage policies regarding the treatment of presbycusis.

*b. Utilize the Preventive Focus of the ACA to Advocate Amending the Medicare Statute to Cover Hearing Aids*

The abundant variety of preventive services mandated under the ACA and the links between untreated presbycusis and other medical conditions would, but for Medicare’s statutory exclusion, warrant Medicare coverage of hearing aids. First, hearing aids themselves are preventive services. Second, the screening for and treatment of presbycusis should be included in the depression screening that the ACA mandates. Given that the ACA, standing alone, would provide for insurance coverage for hearing aids, the Medicare

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<sup>238</sup> *Id.* According to a summary of the ACA from Health Policy Alternatives dated April 2010, “The Secretary must select models for testing where there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.” HEALTH POLICY ALTERNATIVES, SUMMARY OF PATIENT PROTECTION AND AFFORDABLE CARE ACT 86 (Apr. 20, 2010), <http://www.acscan.org/pdf/healthcare/implementation/PPACA-HPA-summary.pdf> [<https://perma.cc/Q5WP-G5N2>].

<sup>239</sup> See HEALTH POLICY ALTERNATIVES, *supra* note 238, at 22–23. Those beneficiaries who participate in both Medicare and Medicaid are known as “dual eligibles.” See, e.g., *Dual Eligible Beneficiaries Under the Medicare and Medicaid Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 2016), [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare\\_Beneficiaries\\_Dual\\_Eligibles\\_At\\_a\\_Glance.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf) [<https://perma.cc/6ZNB-BEBY>].

<sup>240</sup> *Innovation Models*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/#views=models> [<https://perma.cc/WZ65-KBM7>].

statute should be amended to be consistent with the ACA's philosophy and provisions.

*i. Hearing Aids as Preventive Services*

The negative medical consequences of untreated hearing loss among the elderly are well documented.<sup>241</sup> These adverse medical conditions may be prevented, or at a minimum mitigated, by insurance coverage of regular hearing screenings and the provision of hearing aids when indicated. Therefore, both the screenings and the hearing aids can and should be considered preventive services under the ACA. This argument is particularly persuasive given the relatively new evidence of a link between hearing loss and dementia<sup>242</sup> and the uncontroverted evidence that hearing devices enhance quality of life.<sup>243</sup> The Secretary's authority under the ACA permits her to modify the list of preventive services,<sup>244</sup> and such coverage is consistent with the ACA as written. Such a change would further enhance arguments for eliminating Medicare's current statutory exclusion.

The path to include hearing aids as a preventive service is through the USPSTF, which recommends to CMS the preventive services that should be mandatory.<sup>245</sup> To formulate its recommendations, the USPSTF relies on the work of the Evidence-based Practice Center ("EPC"),<sup>246</sup> which reviews and evaluates existing scientific, evidence-based literature. After analyzing the evidence, the USPSTF "grades" the preventive services, and those receiving an "A" or "B" grade are included in the list of mandatory preventive ser-

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<sup>241</sup> See *supra* Part II.

<sup>242</sup> See Lin et al., *supra* note 7, at 214.

<sup>243</sup> See *supra* Part II.

<sup>244</sup> 42 U.S.C.A. § 1315a(d)(3) (West 2015).

<sup>245</sup> The original role of the USPSTF was to recommend the standard medical care that primary care physicians should provide and to whom. Paul Bernstein, *Prevention of Illness*, 12 MARQ. ELDER'S ADVISOR 157, 162 (2010) (providing a history and summary of the role of the USPSTF). Today, policy makers, public and private insurers, research organizations, and professional associations rely on the USPSTF's recommendations. Janell Guirguis-Blake et al., *Current Processes of the U.S. Preventive Services Task Force: Refining Evidence-Based Recommendation Development*, 147(2) ANNALS INTERNAL MED. 117, 117 (2007). The USPSTF, composed of private sector experts in prevention and primary care, examines the scientific evidence supporting a particular medical service, makes recommendations, and develops a future research agenda. Bernstein, *supra*, at 162. While some consider the USPSTF "unbiased, independent and meticulous" and "the 'gold standard' of preventive health services," *id.*, others have accused it of becoming politicized, particularly in the context of the health care reform debate, see, e.g., Editorial, *Senate Health Care Follies*, N.Y. TIMES (Dec. 6, 2009), <http://www.nytimes.com/2009/12/06/opinion/06sun1.html> [<https://perma.cc/G9FJ-QK4D>]. For a response to those critics, see Joseph W. Stubbs, *Statement on the Politicization of Evidence-based Clinical Research*, AM. COLL. PHYSICIANS (Nov. 24, 2009), [http://www.eureka.lert.org/pub\\_releases/2009-11/acop-sot112409.php](http://www.eureka.lert.org/pub_releases/2009-11/acop-sot112409.php) [<https://perma.cc/KY4J-KZER>].

<sup>246</sup> Bernstein, *supra* note 245, at 162–63.

vices.<sup>247</sup> Significantly, the Task Force's recommendations do not take cost considerations into account.<sup>248</sup>

USPSTF's 1996 recommendation on hearing stated that "[s]creening older adults for hearing impairment . . . and making referrals for abnormalities when appropriate, is recommended."<sup>249</sup> The most recent USPSTF statement regarding hearing loss and older adults was issued in 2012 and is a departure from its 1996 statement. The 2012 recommendation, addressing asymptomatic screenings, was based on evidence available through 2010. The recommendation included an "I" statement, a finding of insufficient evidence to make a decision.<sup>250</sup> In 2012, the USPSTF concluded that "the current evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in asymptomatic adults aged 50 years or older."<sup>251</sup> However, the 2012 statement also noted the underreporting of hearing loss due to stigma, the public's reluctance to utilize hearing devices, the subtle and gradual onset of hearing loss among the elderly, and the effect of other diseases and impairments on self-reported hearing loss.<sup>252</sup> At least one study suggests that testing with a tone-emitting otoscope is inexpensive and efficient,<sup>253</sup> and the USPSTF acknowledged that hearing tests cause no harm.<sup>254</sup>

<sup>247</sup> *Grade Definitions*, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 2014), <http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm> [<https://perma.cc/G8YP-TAF4>]. An "A" grade is assigned if "there is high certainty that the net benefit is substantial." *Id.* A "B" grade is assigned if there is "high certainty that the net benefit is moderate" or "moderate certainty that the net benefit is moderate to substantial." *Id.* The USPSTF may also conclude that a preventive service is not worthy of a recommendation for or against (a "C" grade), or that the evidence is insufficient to make a determination (an "I" grade). *Id.*

<sup>248</sup> Bernstein, *supra* note 245, at 163.

<sup>249</sup> U.S. PREVENTIVE SERVS. TASK FORCE, SCREENING FOR HEARING IMPAIRMENT, *in* GUIDE TO CLINICAL PREVENTIVE SERVICES: REPORT OF THE U.S. PREVENTIVE SERVICES TASK FORCE (2d ed. 1996), <http://www.ncbi.nlm.nih.gov/books/NBK15501/> [<https://perma.cc/9FCU-6LBU>].

<sup>250</sup> *Grade Definitions*, *supra* note 247.

<sup>251</sup> *Hearing Loss in Older Adults: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (July 2015), <http://www.uspreventiveservicestaskforce.org/uspstf11/adultheating/adulthearts.htm> [<https://perma.cc/ANW8-9E6J>]; see also Virginia A. Moyer, *Screening for Hearing Loss in Older Adults: U.S. Preventive Services Task Force Recommendation Statement*, 157(9) ANNALS INTERNAL MED. 655, 660 (2012). The 2012 recommendation may also reflect changes in the USPSTF method of evidence review and assessment as well as in the recommendation statement itself, changes developed between 2001 and 2007. See Mary B. Barton et al., *How to Read the New Recommendation Statement: Methods Update from the U.S. Preventive Services Task Force*, 147 ANNALS INTERNAL MED. 123, 123–27 (2007).

<sup>252</sup> See *Final Recommendation Statement: Hearing Loss in Older Adults: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Dec. 2014), <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hearing-loss-in-older-adults-screening> [<https://perma.cc/RXP5-DUWS>]. In its recommendation, the USPSTF also cited a study on the positive impact of hearing aids, noting "quality-of-life improvements, including social, affective, cognitive and physical domains." *Id.* (citing Cynthia D. Mulrow et al., *Quality-of-life Changes and Hearing Impairment. A Randomized Trial*, 113 ANNALS INTERNAL MED. 188, 188 (1990)); Moyer, *supra* note 251, at 658.

<sup>253</sup> See Liu et al., *supra* note 172, at 240 (reporting on a study among veterans 50 years of age or older screened through one of three mechanisms, with the effectiveness measure being hearing aid use one year later). See generally C.W. Watson et al., *Telephone Screening Tests for Functionally Impaired Hearing: Current Use in Seven Countries and Development of a US*

Finally, the USPSTF statement acknowledged that “the cost of a hearing aid is a barrier to use for many older adults because it is not covered by Medicare and many private insurance companies.”<sup>255</sup>

At the time of the USPSTF’s 2012 recommendation regarding asymptomatic screening, many of the evidence-based research findings on the link between hearing loss among the elderly and other medical problems, including dementia, were not yet available. The USPSTF should reexamine its standard in light of this powerful new evidence and conclude, given current medical research and the other factors noted in its 2012 recommendation on screening, that an “A” or “B” recommendation is indicated. Such a recommendation would result in the addition of hearing screenings and devices to the list of mandated preventive services.

*ii. Incorporate the Screening and Treatment of Presbycusis into Mandatory Depression Screenings*

The mandatory “Welcome to Medicare” visit requires a depression screening for all seniors,<sup>256</sup> as do the required annual prevention visits.<sup>257</sup> “Essential Health Benefits,” required for individual and small group plans as well as for Medicaid, also require depression screening as a preventive service for all adults.<sup>258</sup> It is well documented that untreated presbycusis causes isolation, which often leads to depression.<sup>259</sup> Research indicates that “[u]ncorrected hearing loss gives rise to a poorer quality of life, related to isolation, reduced social activity, a feeling of being excluded, and increased symptoms of depression.”<sup>260</sup> A depression screening that does not also include, at a minimum, screening for and treatment of those medical conditions that can cause depression has limited utility. It would be unthinkable to conduct a screening for another serious condition such as heart disease, but then not provide insurance coverage for the patient’s high blood pressure that contributes to the heart disease. Given the link between hearing loss and depression, failure to include hearing screening and treatment as part of a

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*Version*, 23(10) *J. AM. ACAD. OF AUDIOLOGY* 757 (2012) (describing a national telephone hearing test modeled on one used in seven other countries that can be taken at [www.nationalhearingtest.org](http://www.nationalhearingtest.org)).

<sup>254</sup> See Moyer, *supra* note 251, at 656 (“Adequate evidence shows that the harms of treatment of hearing loss in older adults are small to none.”).

<sup>255</sup> *Final Recommendation Statement: Hearing Loss in Older Adults: Screening*, *supra* note 252.

<sup>256</sup> See *Your “Welcome to Medicare” Preventive Visit*, *CTRS. FOR MEDICARE & MEDICAID SERVS.*, <http://www.medicare.gov/people-like-me/new-to-medicare/welcome-to-medicare-visit.html> [<https://perma.cc/NQK6-NYC4>].

<sup>257</sup> See *Depression Screenings*, *MEDICARE*, <https://www.medicare.gov/coverage/depression-screenings.html> [<https://perma.cc/H5YL-KACF>].

<sup>258</sup> See *Preventive Care Benefits for Adults*, *CTRS. FOR MEDICARE & MEDICAID SERVS.*, <https://www.healthcare.gov/preventive-care-adults/> [<https://perma.cc/SV7Z-8YJK>].

<sup>259</sup> See Arlinger, *supra* note 144, at 2S17.

<sup>260</sup> *Id.* at 2S20; see also Gates & Mills, *supra* note 21, at 1116 (“People with depression and cognitive dysfunction should be assessed to exclude occult hearing loss as a contributing factor.”).

depression screening is contrary to the preventive care philosophy embodied in the statute.<sup>261</sup> Because recommending a hearing device for those with hearing loss would assist in alleviating depression, insurance coverage of both the screening and treatment should be required under these provisions, creating more impetus for repeal of Medicare's statutory hearing aid exclusion.

### C. Amending the Medicare Statute in Light of the ACA

Today's climate of preventive care creates an opportunity to bring the two major health reform initiatives of the last sixty years into sync with one another. As indicated, the ACA's mandated prevention services provide the foundation for repeal of Medicare's statutory hearing aid exclusion. Three bills pending as of the date of this Article address this issue. The most straightforward proposal is the "Seniors Have Eyes, Ears, and Teeth Act," H.R. 3308, introduced by Representative Alan Grayson in July 2015.<sup>262</sup> This legislation proposes to expand Medicare coverage by removing the explicit statutory language excluding coverage for hearing aids, eyeglasses, and dental expenses.<sup>263</sup> Although the legislation has 116 sponsors as of March 2016, it is not expected to pass.<sup>264</sup>

The second proposal, the "Help Extend Auditory Relief (HEAR) Act of 2015," adds "aural rehabilitation" to the definition of covered "medical and other services."<sup>265</sup> It also adds hearing aids to the list of covered durable medical equipment.<sup>266</sup> The legislation further defines "hearing rehabilitation" to include services provided by a physician or audiologist, services including aural rehabilitation, audiologic assessments, and "a threshold test to determine audio acuity."<sup>267</sup> The HEAR Act defines a hearing aid as "any wearable instrument or device for, offered for the purpose of, or represented as aiding individuals with, or compensating for hearing loss."<sup>268</sup> Another bill, the "Medicare Hearing Aid Coverage Act of 2015," would delete the hearing aid coverage exclusion and require a study reviewing program pro-

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<sup>261</sup> Gates & Mills, *supra* note 21, at 1116.

<sup>262</sup> Seniors Have Eyes, Ears, and Teeth Act, H.R. 3308, 114th Cong. (2015).

<sup>263</sup> *Id.*

<sup>264</sup> See, e.g., H.R. 3308: *Seniors Have Eyes, Ears, and Teeth Act*, GovTRACK, <https://www.govtrack.us/congress/bills/114/hr3308> [<https://perma.cc/E8EQ-VX8Q>] (giving H.R. 3308 a 0% chance of passage, in part because all of the co-sponsors are members of the minority party).

<sup>265</sup> Help Extend Auditory Relief (HEAR) Act of 2015, H.R. 2748, 114th Cong. § 2(a)(3)(GG) (2015).

<sup>266</sup> *Id.*

<sup>267</sup> *Id.* at § 2(c).

<sup>268</sup> *Id.* at § 2. This definition eliminates current distinctions between hearing aids, said to enhance hearing, and cochlear implants and BAHA devices, which replace hearing. The HEAR Act provides that a hearing aid is available every three years for individuals who meet other statutory requirements. *Id.*

visions providing coverage of hearing aids, with recommendations for potential changes.<sup>269</sup>

Other, less ambitious efforts to address the expense of hearing aids also are pending. Bills have been introduced in both the Senate and in the House of Representatives that would provide a tax deduction up to \$500 for the cost of a qualified hearing aid.<sup>270</sup> Taking an alternative approach, the “Audiology Patient Choice Act of 2015” would enable patients to obtain care from an audiologist without being under the care of a physician, thus reducing patient costs.<sup>271</sup> This legislation as well as the tax credit proposals would reduce the costs of securing hearing aids, but they would not provide sufficient coverage for many Medicare recipients.

Another bill, the Medicare Audiology Services Enhancement Act of 2015, amends the Medicare statute to include “audiology services.”<sup>272</sup> Audiology services are defined as the following services provided by an audiologist, pursuant to a physician’s order or referral: hearing and balance assessment services; auditory treatment services, including auditory processing and auditory rehabilitation treatment; vestibular treatment services; and “intraoperative neurophysiologic monitoring services.”<sup>273</sup> This legislation expands audiologists’ role beyond diagnosis to include treatment, while retaining the physician referral requirement.<sup>274</sup>

The ACA’s philosophy and mandated provisions support the elimination of Medicare’s statutory exclusion of hearing aid coverage. Undoubtedly, one reason for the previous lack of success in eliminating this statutory exclusion is the cost of providing hearing aids to the many people who need them. These costs were explicitly acknowledged as recently as the fall of 2015 when the PCAST noted that this factor has prevented Congressional support for amending the Medicare law.<sup>275</sup> PCAST suggested that reforms in the marketing and bundling of hearing aids could reduce costs, and consequently “the analysis and potential for Congressional action would change.”<sup>276</sup>

Arguments for the elimination of the hearing aid exclusion are augmented by the demonstrated relationship between age-related hearing loss

<sup>269</sup> See Medicare Hearing Aid Coverage Act of 2015, H.R. 1653, 114th Cong. (2015).

<sup>270</sup> See Hearing Aid Assistance Tax Credit Act, S. 315, 114th Cong. (2015); Hearing Aid Assistance Tax Credit Act of 2015, H.R. 1882, 114th Cong. (2015).

<sup>271</sup> Audiology Patient Choice Act of 2015, H.R. 2519, 114th Cong. (2015); see also Medicare Telehealth Parity Act of 2015, H.R. 2948, 114th Cong. (2015) (expanding the telehealth program geographically, and expanding the definition of services to include audiology services, replacing “physician and practitioner” with “physician and professional,” and then defining “professional” to include “audiologist”).

<sup>272</sup> See Medicare Audiology Services Enhancement Act of 2015, H.R. 1116, 114th Cong. (2015).

<sup>273</sup> *Id.* For an analysis of this legislation, see *Know the Facts: H.R. 1116*, AM. SPEECH-LANGUAGE HEARING ASS’N, <http://www.asha.org/Advocacy/Know-the-Facts-About-HR-1116> [<https://perma.cc/7XFB-K9S5>].

<sup>274</sup> See *Know the Facts: H.R. 1116*, *supra* note 273.

<sup>275</sup> Letter from PCAST, *supra* note 14, at 2.

<sup>276</sup> *Id.*

and dementia as well as the uncontroverted evidence that hearing loss causes isolation, depression, cognitive changes, and increased falls.<sup>277</sup> Although providing coverage of hearing devices would likely result in additional costs,<sup>278</sup> treating each condition impacted by hearing loss is also expensive. Appropriately treating the underlying condition, the hearing loss itself, could well result in substantial savings from a reduced need to treat the related conditions and is an issue that, at a minimum, should be explored in evidence-based research.<sup>279</sup> Acknowledging the importance of cost concerns, medical researchers are now concluding that “equal consideration must be given to the societal and health care costs incurred by not enabling access to assistive devices that may prevent or delay the expensive consequences of sensory impairments.”<sup>280</sup> Given the high percentage of seniors affected by presbycusis and the other health conditions to which it contributes, providing Medicare coverage for hearing aids may well save money and will undoubtedly improve the quality of life for many.<sup>281</sup>

#### D. *The ACA and Medicaid Coverage of Hearing Aids*

##### 1. *Preventive Services Argument*

The Medicaid program, the federal-state partnership program that provides health insurance for people who have low incomes, provides limited coverage for hearing aids. In its current form, it could potentially assist those receiving Medicare and Medicaid, as well as those “young” seniors not yet eligible for Medicare<sup>282</sup> and those enrolling in Medicaid through the ACA’s Medicaid expansion provision (in those states opting to participate).<sup>283</sup>

However, twenty-one states and the District of Columbia provide no Medicaid coverage at all for hearing devices for adults.<sup>284</sup> In those states

<sup>277</sup> See *supra* Part II.

<sup>278</sup> Determining the actual costs of providing hearing devices through Medicare is beyond the scope of this article. The pending legislative proposals that would provide for Medicare coverage of hearing devices do not, as of the date of publication, contain fiscal notes estimating the costs of implementation.

<sup>279</sup> Further discussion on the impact of providing preventive services on the cost of medical care is worthy of substantial discussion, but beyond the scope of this article.

<sup>280</sup> Whitson & Lin, *supra* note 23, at 1739.

<sup>281</sup> Expanding Medicare law in this fashion has the potential to affect both the Medicaid and private insurance market, even in the absence of statutory or regulatory changes to those programs. See, e.g., Kinney, *supra* note 181, at 256 (“State Medicaid programs and private payers are greatly influenced by the policy developments in the Medicare program and often follow Medicare policy.”).

<sup>282</sup> See *Seniors & Medicare and Medicaid Enrollees*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Population/Medicare-Medicaid-Enrollees-Dual-Eligibles/Seniors-and-Medicare-and-Medicaid-Enrollees.html> [https://perma.cc/283Q-MFUY].

<sup>283</sup> See *supra* notes 107–108.

<sup>284</sup> See *Medicaid Regulations*, *supra* note 112. For a list of coverage by state, see *Medicaid Benefits: Hearing Aids*, KAISER FAM. FOUND., <http://kff.org/medicaid/state-indicator/hearing-aids/> [https://perma.cc/26YU-MBRE].

offering some Medicaid coverage, the coverage amount often is capped and the plans frequently exclude coverage for fittings or repairs after the warranty has expired, for servicing of hearing aids, and for certain types of hearing devices.<sup>285</sup> The result is devices and services that remain unaffordable for many.

The ACA offers some assistance. The arguments outlined above for coverage via the preventive services provisions of the ACA apply to some Medicaid recipients needing hearing devices. The ACA requires Medicaid programs to provide the preventive services recommended by the USPSTF to newly eligible, adult Medicaid recipients.<sup>286</sup> Additionally, the ACA provides a financial incentive to states to include preventive services at no cost to all recipients.<sup>287</sup> For those eligible before the enactment of the ACA and those in the states that elect to receive the financial incentive, the preventive services arguments raised with respect to Medicare apply to Medicaid with equal or greater force. Because Medicaid has no statutory exclusion of hearing aids, arguments for coverage under Medicaid, read in conjunction with the ACA, are even stronger than those made in the Medicare context.

## 2. *Rehabilitative and Habilitative Services Argument*

The ACA requires most insurance plans to include EHB and those offered under Medicaid to include “Alternative Benefit Plans” that essentially mirror the requirements for EHB.<sup>288</sup> While the ACA defines the categories of EHB that plans must provide, the specifics are defined at the state level.<sup>289</sup> The Act states that each state may designate a “benchmark plan,”<sup>290</sup> with individual plans following its requirements.<sup>291</sup> If the state’s identified benchmark plan does not include the required categories of benefits, HHS may supplement it.<sup>292</sup> If the selected plan fails to include rehabilitative and habilitative services, the state may determine which services should be pro-

<sup>285</sup> *Medicaid Regulations*, *supra* note 112.

<sup>286</sup> See Alexandra Gates et al., *Coverage of Preventive Services for Adults in Medicaid*, KAISER FAM. FOUND. (Nov. 13, 2014), <http://kff.org/medicaid/issue-brief/coverage-of-preventive-services-for-adults-in-medicaid/> [<https://perma.cc/C22F-VTND>].

<sup>287</sup> See generally *id.*

<sup>288</sup> See VICKI WACHINO, CTRS. FOR MEDICARE & MEDICAID SERVS., CMCS INFORMATIONAL BULLETIN: ALTERNATIVE BENEFIT PLAN CONFORMING CHANGES (Jan. 28, 2016), <https://www.medicare.gov/federal-policy-guidance/downloads/CIB-01-28-16.pdf> [<https://perma.cc/4GT9-RHVL>]; see also Mann, *supra* note 193 (describing the relationship between EHB and Alternative Benefit Plans within Medicaid).

<sup>289</sup> *Information on Essential Health Benefits (EHB) Benchmark Plans*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/ccio/resources/data-resources/ehb.html> [<https://perma.cc/VFF2-RC46>] [hereinafter *EHB Benchmark Plans*].

<sup>290</sup> 45 C.F.R. § 156.100 (2016).

<sup>291</sup> SABRINA CORLETTE ET AL., COMMONWEALTH FUND, REALIZING HEALTH REFORM’S POTENTIAL 2 (Mar. 2013), [http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2013/Mar/1677\\_Corlette\\_implementing\\_ACA\\_choosing\\_essential\\_hlt\\_benefits\\_reform\\_brief.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2013/Mar/1677_Corlette_implementing_ACA_choosing_essential_hlt_benefits_reform_brief.pdf) [<https://perma.cc/RNE4-96LC>].

<sup>292</sup> 45 C.F.R. § 156.110(c) (2016).

vided in that category.<sup>293</sup> Finally, the regulations state that if the state plan does not include habilitative services as required, health plans still must provide such services.<sup>294</sup>

Among the EHB the ACA mandates for individual and small group plans and for Medicaid recipients—albeit under a different name—are rehabilitative and habilitative services and devices.<sup>295</sup> Those terms have been defined in a uniform glossary of definitions that health plans for individuals, plans in the exchange, and group plans must provide in a standard statement of benefits and coverage.<sup>296</sup> Final regulations have been promulgated regarding some of the relevant definitional provisions.<sup>297</sup> The glossary itself, developed with the assistance of the National Association of Insurance Commissioners (“NAIC”), was finalized on August 17, 2015.<sup>298</sup> It defines “rehabilitation services” as:

Health care services that help a person *keep, get back or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled*. These services may include physical and occupational therapy, speech-language pathology and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.<sup>299</sup>

“Habilitation services” are defined as:

<sup>293</sup> *Id.* at § 156.110(f); *see also EHB Benchmark Plans*, *supra* note 289.

<sup>294</sup> 45 C.F.R. § 156.115(a)(5) (2016). Plans are required to provide services “in a manner that meets one of the following: (i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings; (ii) Do not impose limits on coverage of habilitative services and devices that are less favorable than any such limits imposed on coverage of rehabilitative services and devices; and (iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.” *See also EHB Benchmark Plans*, *supra* note 289.

<sup>295</sup> *EHB Benchmark Plans*, *supra* note 289. EHB “include items and services in the following ten benefit categories: (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.” *Id.* For similar requirements in the Medicaid program, *see WACHINO*, *supra* note 288.

<sup>296</sup> *Summary of Benefits & Coverage & Uniform Glossary*, CTBS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Consumer-Support-and-Information/Summary-of-Benefits-and-Coverage-and-Uniform-Glossary.html> [<https://perma.cc/8KB3-D2BW>].

<sup>297</sup> Summary of Coverage and Benefits and Uniform Glossary, 80 Fed. Reg. 34,292 (June 16, 2015) (to be codified at 26 C.F.R. 54.9815-2715(c)(2)(i), 29 C.F.R. 2590.715-2715(c)(2)(i), and 45 C.F.R. 147.200(c)(2)(i)).

<sup>298</sup> *Glossary of Health Coverage and Medical Terms*, U.S. DEP’T OF LABOR, <http://www.dol.gov/ebsa/pdf/sbcuniformglossary.pdf> [<https://perma.cc/3B8N-8SUQ>]; Summary of Coverage and Benefits and Uniform Glossary, 80 Fed. Reg. 34,292 (June 16, 2015) (to be codified at 45 C.F.R. 147).

<sup>299</sup> *Glossary of Health Coverage and Medical Terms*, *supra* note 298 (emphasis added).

Health care services that help a person *keep, learn or improve skills and functioning for daily living*. Examples include therapy for a child who isn't walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings.<sup>300</sup>

Although the mandate to provide these services is clear, what the terminology actually means is less clear. The Habilitation Benefits Coalition ("HBC"), formed to advocate for habilitation coverage in the EHB package, offers one of the most useful discussions of these provisions.<sup>301</sup> Advocating for definitions that provide the full range of services and devices for those with disabilities, the HBC relies on congressional testimony to interpret the provisions. It notes the floor statement of Congressman George Miller, who described rehabilitative and habilitative services as including "items and services used to restore functional capacity, minimize limitations on physical and cognitive functions, and maintain or prevent deterioration of functioning."<sup>302</sup> Congressman Bill Pascrell, Jr. offered a similar description of this provision, adding that the goal is to "maintain or prevent deterioration of functioning as a result of an illness, injury, disorder or other health condition."<sup>303</sup>

Commentators acknowledge the challenge of determining the meaning of rehabilitative and habilitative services under the ACA. Some argue that "insurers will likely continue developing their own definitions of coverage for items such as habilitative services, which have not been traditionally covered by insurers."<sup>304</sup> Consequently, internal appeals and external reviews may focus on the meaning of this terminology.<sup>305</sup>

<sup>300</sup> *Id.* (emphasis added).

<sup>301</sup> See generally *Habilitation Benefits Coalition*, HAB: HABILITATION BENEFITS COALITION, <https://habcoalition.wordpress.com/> [<https://perma.cc/CVZ2-FH34>]. The thirty-four-member coalition includes the American Speech-Language-Hearing Association and the Hearing Loss Association of America. See AM. ASS'N ON HEALTH & DISABILITY, *Defining 'Rehabilitative and Habilitative Services and Devices' in the Essential Health Benefits Package Pursuant to Congressional Intent Under the Affordable Care Act 10* (Oct. 20, 2011), <http://www.aahd.us/wp-content/uploads/2012/03/HabilitationBenefitsCoalition101911.pdf> [<https://perma.cc/K3W4-6ETS>].

<sup>302</sup> AM. ASS'N ON HEALTH & DISABILITY, *supra* note 301, at 4 (citing 156 CONG. REC. H1882 (Mar. 21, 2010)).

<sup>303</sup> *Id.* (citing 156 CONG. REC. E462 (Mar. 23, 2010)).

<sup>304</sup> Joseph Friedman et al., *A Crystal Ball: Managed Care Litigation in Light of the Patient Protection and Affordable Care Act*, 27 HEALTH L. 1, 6 (Dec. 2014); see also Wendy K. Mariner, *The Picture Begins to Assert Itself: Rules of Construction for Essential Health Benefits in Health Insurance Plans Subject to the Affordable Care Act*, 24 ANNALS HEALTH L. 437, 439 (2015) (regarding EHB, writing that "both the statute and the regulations speak in broad categorical terms, leaving considerable discretion to insurers to decide what to cover in particular health plans and in individual cases," and then discussing the appropriate application of statutory rules of construction to both the insurance policies and the statutory and regulatory provisions).

<sup>305</sup> Friedman et al., *supra* note 304, at 6.

Although none of the limited interpretations of this particular mandatory EHB mention hearing aids, providing coverage of hearing aids is consistent with the sparse definition offered in the law.<sup>306</sup> Hearing aids restore hearing, assist seniors in maintaining their function in a variety of contexts, and help prevent further deterioration, in particular for those documented medical conditions that may be caused or exacerbated by untreated presbycusis. Therefore, hearing aids should be covered under the rehabilitative and habilitative provisions of the ACA for those enrolled in Medicaid.

As she does in provisions regarding preventive services, the Secretary of HHS has the authority to modify the EHB currently required.<sup>307</sup> Adding hearing devices to those benefits is consistent with the Secretary's authority and the goals of the ACA.

### 3. *Implement a Pilot Project*

As discussed above with respect to Medicare, the Secretary could implement a pilot project testing the viability of providing mandatory hearing aid coverage in the Medicaid program. As with a Medicare pilot, the data from that project could be utilized to evaluate potential enhanced quality of care and the impact on costs.

In light of these arguments, expanding Medicaid coverage could be approached on several levels: (1) adding hearing aids to the list of preventive services; (2) explicitly stating that hearing devices are included in the rehabilitative and habilitative services section of the EHB provisions; (3) advocating for individual Medicaid recipients seeking coverage of hearing devices, including appealing denials of coverage; and (4) urging Congress to mandate that all Medicaid plans provide additional coverage for the costs of hearing devices.<sup>308</sup> Finally, absent a congressional mandate, individual states

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<sup>306</sup> It is also consistent with the definitions recommended by the Habilitation Benefits Consortium, *supra* note 301. *See also* 80 Fed. Reg. 75,517 (proposed Dec. 2, 2015) (addressing coverage of non-EHB in benchmark plans, stating that plans may not include "routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or nonmedically necessary orthodontia as EHB.") Notably, hearing aids have not been included on this list. *Id.*

<sup>307</sup> 42 U.S.C.A. § 1395m(n)(1) (West 2015). For further discussion of the Secretary's role regarding EHB, see DeBoer, *supra* note 16, at 535–40.

<sup>308</sup> Because Medicaid is a joint federal-state program, Congress sets the minimum required services that states must cover. Jean Hearne & Julie Topoleski, *An Overview of the Medicaid Program*, CONG. BUDGET OFF. (Sept. 18, 2013), <https://www.cbo.gov/publication/44588> [<https://perma.cc/8QAM-Y3CS>]; *see also Benefits*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/medicaid-benefits.html> [<https://perma.cc/8N4N-5MM3>]. For example, in the Medicaid program for Children, Early and Periodic Screening Diagnostic and Treatment ("EPSDT"), the federal government mandates the coverage of hearing screenings and treatment. *See, e.g., Early and Periodic Screening, Diagnostic, and Treatment*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html> [<https://perma.cc/CMV3-MK25>]

should expand their Medicaid coverage to be consistent with the ACA's preventive care provisions.<sup>309</sup>

### E. *The ACA and Private Insurance Coverage of Hearing Aids*

The arguments above regarding coverage of hearing devices under the rehabilitative and habilitative categories of EHB apply to policies in the private sector as well. If these arguments prove unsuccessful, the passage of the ACA renders strategies for greater mandated private insurance coverage of hearing devices at the state level a harder sell, ironically.<sup>310</sup> As indicated, each state must have a "benchmark plan" applicable to individual and small group markets,<sup>311</sup> with each plan providing the defined EHB.<sup>312</sup> If states decide to expand the list of EHB, states are obligated to pay either the enrollee or the insurer for the costs of those additional health benefits.<sup>313</sup> Although the insured are responsible for cost sharing, including deductibles, copays, and co-insurance, those costs are limited and annual and lifetime limits cannot be applied to EHB,<sup>314</sup> resulting in greater costs to the states if they expand the list of EHB. A state-by-state examination of the approved benchmark plans demonstrates that only Hawaii, which offers coverage of

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("Hearing services must include, at a minimum, diagnosis and treatment for defects in hearing, including hearing aids.").

<sup>309</sup> This interpretation of the ACA and explicit expansion of the ACA, even if successful, would leave the many low- and moderate- income seniors not quite "poor enough" for Medicaid to fend for themselves.

<sup>310</sup> Independently of the ACA, some states have legislated coverage of hearing aids. *See, e.g., State Hearing Health Insurance Mandates*, HEARING LOSS ASS'N AMERICA (Jan. 2014), <http://hearingloss.org/content/state-hearing-health-insurance-mandates> [<https://perma.cc/9XKK-MXHC>]. However, most of this coverage is for those under the age of 18, and when adults are covered, the amount is generally quite limited. *Id.*

<sup>311</sup> *EHB Benchmark Plans*, *supra* note 289. If states refuse to identify a benchmark plan, a default plan applies. 42 C.F.R. § 156.100 (2015).

<sup>312</sup> An exception to this are plans that are grandfathered, which include job-based plans that have not significantly reduced benefits or increased costs since March 2010 and individual plans for people that were enrolled prior to March 2010. *See Grandfathered Health Insurance Plans*, HEALTHCARE.GOV, <https://www.healthcare.gov/health-care-law-protections/grandfathered-plans/> [<https://perma.cc/E49M-SFU9>].

<sup>313</sup> 42 U.S.C. § 18031(d)(3) (2012); *see also Quick Take: Essential Health Benefits: What Have States Decided for Their Benchmark?*, KAISER FAM. FOUND. (Dec. 7, 2012), <http://kff.org/health-reform/fact-sheet/quick-take-essential-health-benefits-what-have-states-decided-for-their-benchmark/> [<https://perma.cc/J7FP-KQT5>] ("The ACA specifies that if states require plans to cover services beyond those defined as EHBs by the law, for example certain state-mandated benefits, states must defray the costs of those benefits."). Health benefits required by states prior to December 31, 2011 are defined by regulation as not "additional EHB" and therefore states are not required to reimburse enrollees or insurers for them. *EHB Benchmark Plans*, *supra* note 289.

<sup>314</sup> 45 CFR § 147.126. Individuals are, however, responsible for premiums and out-of-pocket expenses. 42 U.S.C.A. § 18022(c)(3)(A) (West 2014). The cap on cost-sharing does not include premiums or spending on non-covered services. *Id.* at § 18022(c)(3)(B).

hearing aids up to every sixty months,<sup>315</sup> has added hearing aids to its list of expanded EHB coverage.<sup>316</sup>

One incentive private employers may have to incorporate hearing aid coverage into their plans is the growing number of seniors remaining in the workforce.<sup>317</sup> Private, employee-based insurance represents the largest sector of the health insurance market.<sup>318</sup> An increasing number of seniors are postponing retirement and continuing in the workforce, largely due to financial insecurity.<sup>319</sup> Some of those over fifty, and certainly many over sixty-five, will experience age-related hearing loss.<sup>320</sup> Mandating insurance coverage for assistive hearing devices, including hearing aids where appropriate, will enable older employees to remain in the work force longer and encourage employers to retain experienced employees able to work at maximum productivity.<sup>321</sup>

## VI. RECOMMENDATIONS

The philosophy embodied in the ACA affirms the necessity of insurance coverage of hearing aids for seniors. Specific provisions in the Act and its underlying philosophy are useful catalysts for amending the Medicare law to eliminate the statutory exclusion and provide coverage for hearing screenings and devices. Although past efforts to do so were stymied, the ACA and empirical evidence demonstrating the relationship between presbycusis and other medical conditions alter the dynamic. Now is the time, as the health care and insurance industries continue adapting to comply with the

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<sup>315</sup> HAW. DEP'T OF COMMERCE & CONSUMER AFFAIRS, PPACA ESSENTIAL HEALTH BENEFITS – BENCHMARK BENEFITS PACKAGE 5, [http://files.hawaii.gov/dcca/ins/Benchmark%20Benefit%20Package%20Grid\\_Final%20for%20DCCA%20Site.pdf](http://files.hawaii.gov/dcca/ins/Benchmark%20Benefit%20Package%20Grid_Final%20for%20DCCA%20Site.pdf) [<https://perma.cc/P9V4-R2K2>].

<sup>316</sup> *EHB Benchmark Plans*, *supra* note 289. In some states, coverage that existed prior to the ACA is maintained on the list of required benefits.

<sup>317</sup> Philip Moeller, *Challenges of an Aging American Workforce*, U.S. NEWS & WORLD REP. (June 19, 2013, 11:50 AM), <http://money.usnews.com/money/blogs/the-best-life/2013/06/19/challenges-of-an-aging-american-workforce> [<https://perma.cc/8WR2-V4VQ>].

<sup>318</sup> Cogan, *supra* note 180, at 361.

<sup>319</sup> *See, e.g.*, Don Lee, *More Older Workers Making Up Labor Force*, L.A. TIMES (Sept. 4, 2012), <http://articles.latimes.com/2012/sep/04/business/la-fi-labor-seniors-20120903> [<https://perma.cc/4LKK-BL6M>].

<sup>320</sup> *Basic Facts About Hearing Loss*, HEARING LOSS ASS'N AMERICA, <http://www.hearing-loss.org/content/basic-facts-about-hearing-loss> [<https://perma.cc/9UR4-TQKU>] (noting that approximately twenty percent of adults in the United States report some degree of loss, and at age 65, one out of three individuals has a hearing loss).

<sup>321</sup> A senior with presbycusis and still in the workforce may well have an ADA argument if an employer fails to accommodate her hearing loss. *See* Equal Emp't Opportunity Comm'n v. Branch Banking & Tr. Co., 571 F. Supp. 2d 682, 685 (E.D.N.C. 2008) (finding material issue of fact as to whether employer failed to reasonably accommodate for disabled employee's hearing loss); *see also* *Jeffries v. Verizon*, No. CV 10–2686, 2012 WL 4344197, at \*17 (E.D.N.Y. Aug. 31, 2012) (recommending summary judgment be denied to employer in regards to defendant employer's failure to accommodate claim due to his hearing loss). The role of the ADA in requiring employers to provide hearing devices is beyond the scope of this article.

ACA, to develop the robust coalitions necessary to make this statutory change a reality.

Absent that statutory change, the ACA presents very specific opportunities to argue for hearing aid coverage for Medicare and Medicaid recipients and those with private insurance. Advocating the implementation of pilot projects providing this coverage to Medicare and Medicaid recipients is one strategy. Other strategies include lobbying the Secretary to add hearing devices to the list of preventive services and EHB, and arguing for coverage under existing preventive services and EHB provisions. These strategies should be pursued on behalf of individual beneficiaries and also in a broader, systemic fashion. Making these arguments forcefully will require motivated advocates and willing clients, and hearing aid providers comfortable with testing these theories.

Additionally, it is critical to lobby and coordinate with regulators, particularly at CMS, to adopt regulations and coverage decisions allowing for these interpretations of the ACA. CMS's recent position reversal following a proposal to further limit Medicare coverage of hearing devices illustrates the powerful role of effective regulatory advocacy. Historically, Medicare has covered certain devices including cochlear implants, and brainstem implants,<sup>322</sup> as well as osseointegrated implants,<sup>323</sup> which include the BAHA.

In 2014, CMS proposed revising its definition of hearing devices eligible for Medicare coverage,<sup>324</sup> and specifically proposed excluding the BAHA, which previously had been covered, from Medicare coverage.<sup>325</sup> Responding to comments opposing this change, CMS reversed its position in the Final Rule<sup>326</sup> and continued existing CMS policy treating BAHAs like

<sup>322</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE BENEFIT POLICY MANUAL: GENERAL EXCLUSIONS FROM COVERAGE, CHAPTER 15, at 27–28 (Rev. 198, Nov. 6, 2014), <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf> [<https://perma.cc/7HCW-WQ59>] [hereinafter GENERAL EXCLUSIONS FROM COVERAGE]. Such devices are used when “hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.” *Id.* These devices are defined as “devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.” *Id.*

<sup>323</sup> *Id.* Osseointegrated implants are defined as “devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.” *Id.*

<sup>324</sup> Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 40,207, 40,213–14 (proposed July 11, 2014).

<sup>325</sup> See GENERAL EXCLUSIONS FROM COVERAGE, *supra* note 322; see also CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL, CHAPTER 1, at 89–90 (Rev. 187, Dec. 10, 2015), [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part1.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf) [<https://perma.cc/G2VN-DPCN>].

<sup>326</sup> Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 66,120, 66,241–427 (Nov. 6, 2015) (to be codified at 42 C.F.R. § 411.15(d)(2)). CMS articulated three arguments for its reversal of position: (1) AOIs, like cochlear implants, are in fact implants and therefore considered prosthetic devices covered under other Medicare categories; (2) These devices replace rather than restore or amplify hearing, as do more tradi-

cochlear implants, covering both under Medicare.<sup>327</sup> This revised Final Rule demonstrates the power of effective administrative advocacy and the need for vigilant monitoring of regulatory changes in this arena.<sup>328</sup>

Advocates should lobby the USPSTF to reexamine its position on hearing testing and devices in light of substantial new evidence linking hearing loss to numerous medical conditions, all of which are expensive to treat. The essential preventive services the USPSTF identifies are incorporated into the ACA regulations, and therefore the USPSTF plays a critical role in this process.

To better implement these reforms, advocates for those with presbycusis must develop a common strategy. It is in the interests of consumers with hearing loss as well as professional organizations to support pending initiatives providing Medicare coverage of hearing aids. However, dynamics among the various hearing professional organizations complicate and contribute to the failure of reform efforts. Some organizations promote a particular professional perspective,<sup>329</sup> while others promote the interests of those with hearing loss.<sup>330</sup> Others combine these missions.<sup>331</sup> Exemplifying these

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tional hearing aids; and (3) Because AOIs utilize technologies that did not exist when Medicare was enacted in 1965, Congress could not have intended to exclude them from Medicare coverage. *Id.* Followed to its logical conclusion, this last argument would require that most of the devices used today, which rely on technologies that did not exist in 1965, also be covered.

<sup>327</sup> GENERAL EXCLUSIONS FROM COVERAGE, *supra* note 322.

<sup>328</sup> Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 66,120, 66,241–427 (Nov. 6, 2015) (to be codified at 42 C.F.R. § 411.15(d)(2)).

<sup>329</sup> See, e.g., *About Us*, AM. ACAD. AUDIOLOGY, <http://www.audiology.org/about-us> [<https://perma.cc/4F5R-DT9E>] (“The American Academy of Audiology is the world’s largest professional organization of, by, and for audiologists . . . [and] is dedicated to providing quality hearing care services through professional development, education, research, and increased public awareness of hearing and balance disorders.”); AM. SPEECH-LANGUAGE-HEARING ASS’N, <http://www.asha.org/> [<https://perma.cc/T3HQ-M7QR>] (“The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 182,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech language pathology support personnel; and students.”). The American Academy of Otolaryngology-Head and Neck Surgery (“AAO-HNS”) represents head and neck surgeons who treat the ear, *About Us*, AM. ACAD. OTOLARYNGOLOGY-HEAD & NECK SURGERY, <http://www.entnet.org/content/about-us> [<https://perma.cc/J93X-REVZ>], while the Academy of Doctors of Audiology’s (“ADA”) mission is to offer “programming and support to those audiologists and students who are or who desire to be autonomous practitioners in whatever setting they choose to practice.” *Academy of Doctors of Audiology*, ACAD. DOCTORS AUDIOLOGY, <http://www.audiologist.org/about> [<https://perma.cc/74V5-UM88>]. The ADA’s mission emphasizes practice ownership. *Id.*

<sup>330</sup> See, e.g., *Who We Are*, HEARING LOSS ASS’N AMERICA, <http://www.hearingloss.org/content/who-we-are> [<https://perma.cc/B4LJ-E9PU>] (describing its mission as providing “assistance and resources for people with hearing loss and their families . . . and rais[ing] public awareness about the need for prevention, treatment, and regular hearing screenings throughout life”); see also *Message to Audiologists, Hearing Aid Specialists, Hearing Aid Manufacturers*, HEARING LOSS ASS’N AMERICA (Apr. 2, 2012), <http://www.hearingloss.org/content/message-audiologists-hearing-aid-specialists-hearing-aid-manufacturers> [<https://perma.cc/U8NQ-HC6T>] (responding to debate over United Health Care’s “hiHealth Innovations” effort to provide consumers with hearing aids via phone and other technology). For more information on hi

tensions is the current debate over pending legislation, the Audiology Patient Choice Act, which would permit audiologists to provide hearing services without physician referral or oversight.<sup>332</sup> Naturally, the American Academy of Audiology (“AAA”) supports this legislation,<sup>333</sup> as does the Academy of Doctors of Audiology (“ADA”).<sup>334</sup> The American Academy of Otolaryngology–Head and Neck Surgery (“AAO-HNS”) opposes the legislation because it grants audiologists direct access to Medicare patients, bypassing physician examination or referral.<sup>335</sup> The AAO-HNS supports alternative legislation, the Medicare Audiology Services Enhancement Act of 2015, which the American Speech-Language-Hearing Association (“ASHA”) also supports.<sup>336</sup> The AAA opposes this bill due to the level of physician oversight it requires.<sup>337</sup>

Tensions such as these, particularly those addressing “direct access,” interfere with the development of a coordinated strategy that benefits seniors and others with hearing loss.<sup>338</sup> Advocates for seniors must coordinate with

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Health Innovations, see HiHEALTHINNOVATIONS, <https://www.hihealthinnovations.com> [https://perma.cc/EQ38-PFWY].

<sup>331</sup> See, e.g., *About Us*, COALITION FOR GLOBAL HEARING HEALTH, <http://coalitionforglobalhearinghealth.org/about-us/> [https://perma.cc/J3C9-8EWN] (describing its goals “to advocate for effective hearing health services and policies, to equip and empower hearing healthcare professionals, families, educators, communities and those with hearing loss, and to encourage and perpetuate best practices”). It has a special focus on promoting hearing health services in low-resource communities. *Id.*; see also *Meet the Members*, HEARING INDUS. ASS’N, <http://www.hearing.org/Content.aspx?id=50> [https://perma.cc/F94H-XKSC] (describing itself as an “association of manufacturers of hearing aids, assistive listening devices, component parts, and power sources”).

<sup>332</sup> H.R. 2519, 114th Cong. (2015).

<sup>333</sup> *Academy Endorses Audiology Patient Choice Act*, AM. ACAD. AUDIOLOGY (May 22, 2015), <http://www.audiology.org/advocacy/academy-endorses-audiology-patient-choice-act> [https://perma.cc/PV57-GMGQ].

<sup>334</sup> Stephanie Czuhajewski, *Representative Jenkins and Cartwright Reintroduce the Audiology Patient Choice Act*, H.R. 2519, ACAD. DOCTORS AUDIOLOGY (May 22, 2015), <http://www.audiologist.org/latest-news-archive/1420-rep-jenkins-and-cartwright-reintroduce-apca> [https://perma.cc/PY2P-ZNGU]. The ADA states that the legislation will “improve access to qualified, licensed Medicare providers, by allowing seniors with a suspected hearing or balance disorder to seek evaluation and rehabilitation directly from audiologists, eliminating archaic medical doctor order requirements.” *Know the Facts about the Audiology Patient Choice Act*, ACAD. DOCTORS AUDIOLOGY (May 2015), [http://audiologist.org/\\_resources/documents/18x18/HR2519IssueBrief.pdf](http://audiologist.org/_resources/documents/18x18/HR2519IssueBrief.pdf) [https://perma.cc/62EM-82UR].

<sup>335</sup> Letter from James C. Denny III, Exec. Vice President and CEO, Am. Acad. of Otolaryngology—Head and Neck Surgery, to Speaker John Boehner & Rep. Nancy Pelosi (June 2, 2015), [http://www.entnet.org/sites/default/files/uploads/scope\\_6-2-15\\_aaohns.pdf](http://www.entnet.org/sites/default/files/uploads/scope_6-2-15_aaohns.pdf) [https://perma.cc/C5H9-X66U]. It further states that “it is ‘not a turf issue,’ but a patient safety issue.” *Id.*

<sup>336</sup> *AAO-HNS Supports ASHA Legislation*, AM. ACAD. OTOLARYNGOLOGY, <http://www.entnet.org/content/audiology-scope-practice-issues> [https://perma.cc/3EEA-FKNN]; see also *Support Medicare Coverage of Audiology Services Legislation*, AM. SPEECH-LANGUAGE-HEARING ASS’N, <http://cqrengage.com/asha/app/write-a-letter?2&engagementId=81432> [https://perma.cc/V2GF-WJAD].

<sup>337</sup> *Ask Your Representative to Oppose the Medicare Audiology Services Enhancement Act*, AM. ACAD. AUDIOLOGY, <http://capwiz.com/audiology/issues/alert/?alertid=64237626> [https://perma.cc/6J8S-2RCY].

<sup>338</sup> See *Veterans’ Access to Hearing Health Act of 2015*, H.R. 353, 114th Cong. (2015) (outlining the ongoing debate about Veterans Administration services for veterans with hearing

these and other relevant organizations to collaboratively develop, evaluate, and promote legislative and regulatory policies.<sup>339</sup> Absent a consensus among hearing professionals and advocacy organizations, opponents will exploit internal conflicts to defeat legislative reforms.

## VII. CONCLUSION

Presbycusis is one of the most common conditions of aging, and affects all aspects of an individual's life, including his or her medical condition, mental health, social networks, and overall quality of life. One is hard-pressed to imagine other consequences of aging that affect so many people and have such far-reaching effects. The failure to mandate adequate insurance coverage of hearing devices—primarily through Medicare but also via Medicaid and private insurance—particularly in this climate of preventive care and mandated services, is short-sighted and antiquated. Advocates have ample opportunities and arguments to change this.

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loss and who can provide those services); *AVAA opposes S 564 and HR 353*, ASS'N OF VA AUDIOLOGISTS (Sept. 10, 2015), <http://myavaa.org/2015/09/10/avaa-opposes-s-564-and-hr-353/> [<https://perma.cc/4QKX-BL9Z>] (highlighting opposition to services provided by hearing aid specialists as opposed to audiologists); see also *Audiologists Must Continue Advocacy Efforts Against H.R. 353*, AM. SPEECH-LANGUAGE-HEARING ASS'N, (July 27, 2015), <http://www.asha.org/News/2015/Audiologists-Must-Continue-Advocacy-Efforts-Against-HR-353/> [<https://perma.cc/DN5T-W3XB>] (lobbying against the proposed bill and voicing concern about a lack of training by “hearing aid dispensers”). A past issue raising similar tensions was United Health Care's “hiHealth Innovations,” an initiative that offered online hearing tests. The debate among professional organizations with respect to this issue resulted in a Cease and Desist Order from the Food and Drug Administration (FDA) ordering hiHealth Innovations to cease marketing the test. See, e.g., Therese Walden, *The Audiologists Are Coming!*, AM. ACAD. AUDIOLOGY, <http://www.audiology.org/about-us/academy-leadership/board-directors/let-me-hear-you-34> [<https://perma.cc/89CA-72QQ>]; Letter from Steven D. Silverman, Dir., Office of Compliance, Ctr. for Devices & Radiological Health, Dep't of Health & Human Servs., to Lisa Tseng, CEO, hi HealthInnovations (Mar. 28, 2012), [http://www.audiology.org/sites/default/files/documents/20120418\\_hihealthLetter.pdf](http://www.audiology.org/sites/default/files/documents/20120418_hihealthLetter.pdf) [<https://perma.cc/6BKN-XN5X>].

<sup>339</sup> A coordinated strategy, such as that implemented in securing other significant reforms in health care and social welfare policy, must include advocacy at the state and federal level, and the use of social media, personal stories, health research and economic data. For an example of a recent success in effectuating systemic change, see, for example, *Roadmap to Victory*, FREEDOM TO MARRY, <http://www.freedomtomarry.org/pages/roadmap-to-victory> [<https://perma.cc/Q3VS-JC6C>].