

# Is Gender Reassignment Surgery "Medically Necessary?"

Peter Sprigg

# **EXECUTIVE SUMMARY \***

#### Introduction

"Transgender" individuals are those "who transiently or permanently identify with a gender different from their natal gender" (that is, from their biological sex at birth). Some (not all) who identify as transgender seek surgery, known as "gender reassignment surgery," to make their bodies resemble that of their preferred gender. While surveys show most who identify as transgender would like to have surgery, many are unable to obtain it due to the high cost, and the fact that many health insurers do not provide coverage for such procedures on the grounds that they are "cosmetic" and/or "elective." Transgender activists are pushing to overcome such barriers by having these procedures declared "medically necessary."

#### **Federal Government Policy**

The largest federal health care program is Medicare, which provides health care to senior citizens. In 1989, the U.S. Department of Health and Human Services (HHS) issued a "National Coverage Decision" (NCD) explicitly denying coverage for "sex reassignment surgery," deeming it "experimental" and warning of "a high rate of serious complications." In 2014, an HHS Departmental Appeals Board overturned the 1989 NCD, ruling that "transsexual surgery is safe" and "effective," thus allowing it to be covered on a case-by-case basis.

In 2016, however, the Centers for Medicare & Medicaid Services under HHS (CMS) declined to issue a new NCD that would *mandate* coverage for such surgery under Medicare, declaring that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes." CMS examined 33 studies, but found that all had "potential methodological flaws," and that "[o]verall, the quality and strength of evidence were low." Patients in the best studies "did not demonstrate clinically significant changes" after surgery. One of the strongest studies, out of Sweden, showed a suicide rate among post-surgical transgender patients that was nineteen times that of the general population.

The 2014 appellate decision was made by three lawyers, with input only from pro-transgender experts and briefs. The 2016 decision memo was based on an original review of the research by a six-member team that included three medical doctors and a Ph.D.

#### Conclusion

The burden of proof must rest on those who claim that gender reassignment surgery is "medically necessary." The 2016 CMS Decision Memo strongly suggests that the evidence is lacking to make this assertion.

\* The Executive Summary does not contain citations as these are embedded in the text of this paper.

# Is Gender Reassignment Surgery "Medically Necessary?"

Peter Sprigg

#### Introduction

According to the American Psychiatric Association, "transgender" individuals are those "who transiently or permanently identify with a gender different from their natal gender."<sup>1</sup> ("Natal gender" is the APA's way of referring to an individual's actual biological sex as identified at birth.) The fundamental goal of the transgender movement is for those who identify as transgender to be fully accepted in the social role of the gender they choose to identify with, regardless of their actual biological sex.

Transgender activists do not believe that such acceptance should be conditioned on any change in their physical bodies. In other words, they assert that a person with male sex organs who identifies as female should be accepted as a "woman," and a person with female sex organs who identifies as male should be accepted as a "man."

However, many individuals who identify as transgender do seek medical interventions in an effort to alter their appearance and physical characteristics in order to make their biological sex less obvious and to make their body resemble that of their preferred gender more closely. Such interventions may include cross-sex hormones (estrogen for a biological male who identifies as female; testosterone for a biological female who identifies as male).

They may also include surgery — most notably, what is colloquially referred to as "top" surgery (a double mastectomy to remove the breasts for a biological female who identifies as male; breast implants for a biological male who identifies as female); or "bottom" surgery (that is, genital surgery — removal of the penis and testicles and construction of an artificial vagina for a biological male who identifies as female; hysterectomy — removal of the uterus — and, less commonly, creation of an artificial penis for the biological female who identifies as male).

Many terms have been used for such surgery through the years. What used to be called "sex change surgery" came to be known as "sex reassignment surgery," then "gender reassignment surgery." More recently, some transgender activists have begun using the term "gender affirmation" or "confirmation" surgery, in an apparent attempt to deny that any "reassignment" by the surgeon is involved, instead asserting that the surgery merely "confirms" the "gender identity" that was innate in the individual despite being contradicted by the person's anatomy.

For purposes of this paper, Family Research Council will employ the term "gender reassignment surgery," reflecting our conviction that "sex" is an innate biological identifier that cannot be altered by surgery. Such surgery instead seeks to facilitate a change in the individual's "gender" (defined in terms of one's social role only).

#### **Obtaining Gender Reassignment Surgery**

A 2011 survey of persons who identified as transgender found that large majorities of them either have had or desire to have gender reassignment surgery, including the major forms of both "top" and

"bottom" surgery.<sup>2</sup> However, in every case, the percentage who "want [a procedure] someday" exceeds the percentage who already "have had" the procedure. Why? The report on the survey (conducted by two pro-transgender activist groups, the National Center for Transgender Equality and National Gay and Lesbian Task Force) explains the issue this way:

The high costs of gender-related surgeries and their exclusion from most health insurance plans render these life-changing (in some cases, life-saving) and medically necessary procedures inaccessible to most transgender people.<sup>3</sup>

#### **Cosmetic and Elective**

The American Board of Cosmetic Surgery says:

The procedures, techniques, and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. . . . Because the treated areas function properly, cosmetic surgery is elective.<sup>4</sup>

Similarly, the American Society of Plastic Surgeons says:

Cosmetic plastic surgery includes surgical and nonsurgical procedures that enhance and reshape structures of the body to improve appearance and confidence. . . . Because it is elective, cosmetic surgery is usually not covered by health insurance.<sup>5</sup>

On the face of it, it would appear obvious that gender reassignment surgery is both "cosmetic" and "elective." That is, its only function is to alter the appearance of the body, not to improve or preserve any biological function.<sup>6</sup> Indeed, several of these procedures actually *destroy* an otherwise healthy body's ability to engage in certain natural functions such as reproduction, gestation, or lactation.

Nevertheless, in order to obtain third-party payment for these expensive procedures, via either private or government health insurance programs, transgender activists have begun insisting (as in the quote from the National Transgender Discrimination Survey above) that gender reassignment surgery is "medically necessary." Such a designation has become crucial to the achievement of transgender goals.

# What Does "Medically Necessary" Mean?

The official U.S. government website for Medicare has a concise definition of "medically necessary," saying that the term applies to:

Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.<sup>7</sup>

The first point to make about this definition is that gender reassignment surgery is plainly *not* something that is needed "to diagnose or treat" any *physical* "illness, injury, condition, disease." Remember, those who identify as transgender have biological sex characteristics that are *physically normal*.<sup>8</sup>

No, the "illness, . . . condition, [or] disease" that is purportedly "treated" by gender reassignment surgery is that of "gender dysphoria" – an entirely *psychological* condition, defined by the American Psychiatric Association as, "Distress that accompanies the incongruence between one's experienced and expressed gender and one's assigned or natal gender."<sup>9</sup>

Normally, one would expect a psychological "illness" to be treated with psychological care – although there are obvious exceptions, such as the use of medications to treat depression. However, the use of *surgery* as the principal treatment for a *mental* condition – the match between the "services" and the "condition" – is even more unusual. A 2014 article in the *American Journal of Public Health* acknowledged this, saying that the designation of "gender dysphoria" as a mental disorder

gives rise to an inherent contradiction in terms: what is presented as a mental condition has recognized medical and surgical treatment:

Gender Dysphoria is a unique condition in that it is a diagnosis made by mental health care providers, although a large proportion of the treatment is endocrinological and surgical.<sup>10</sup>

A more detailed definition of "medically necessary," from a Blue Cross Blue Shield document, is actually cited by the World Professional Association for Transgender Health (WPATH) – the leading medical organization promoting gender reassignment surgery. It says that "medically necessary" services must be:

• • •

(a) in accordance with generally accepted standards of medical practice;

(b) clinically appropriate . . . and considered effective for the patient's illness, injury, or disease; and

(c)  $\dots$  not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic  $\dots$  results  $\dots$ 

Generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature  $\dots$ <sup>11</sup>

# Who Decides What is "Medically Necessary?"

Crafting a definition of "medically necessary" is one thing; applying it to a particular procedure, such as gender reassignment surgery, is something else again. Indeed, it is not even clear *who* should have the authority to make such a decision.

A 2012 news article in the Canadian Medical Association's journal explored this question.<sup>12</sup> It quoted the president of a physicians' organization as saying, "Medical necessity should be determined between the patient and the health care provider." In contrast, a government official was cited as arguing the goal should be "to base spending decisions on evidence instead of the judgment of physicians alone." Meanwhile, a law professor even suggests, "Others who might be able to provide valuable input to the process include ethicists, scientists, public policy experts and philosophers."<sup>13</sup>

A 2014 article in *The Atlantic* similarly warned:

Increasingly, health experts rely on the political system to answer the difficult questions of what should be reimbursable by insurers, Medicare, and Medicaid . . . The fifty states have imposed

more than 2,000 mandates . . . Many of these mandates cover treatments that used to be thought of as cosmetic, optional, or at the very least not medically necessary.

The article suggested the reason is not new medical and scientific advances, but economics:

[H]ealthcare had done what any industry does to increase its market and revenue base in the face of rising consumer demand.... The most important strategy of the healthcare industry has been to endlessly increase our demand for healthcare.<sup>14</sup>

#### **Mixed Precedents**

Different public and private insurers or providers of health care have reached different conclusions about whether gender reassignment surgery (and/or related care such as hormone therapy) is (or may be) medically necessary. In several cases, coverage of such costs has resulted from court cases. For example, a Minnesota judge in 2016 struck down that state's policy against Medicaid coverage for such surgery on grounds that "it covers one medically necessary treatment for gender dysphoria (hormone therapy) and not another (sex-reassignment surgery)."<sup>15</sup> Early in 2017, a convicted murderer in California received state-funded reassignment surgery following the 2015 settlement of a long-running lawsuit. In a statement conceding the legal argument made by lawyers for the biologically male killer who now bears the female name "Shiloh Heavenly Quine," a corrections spokeswoman said:

The Eighth Amendment of the US Constitution requires that prisons provide inmates with medically necessary treatment for medical and mental health conditions, including inmates diagnosed with gender dysphoria.<sup>16</sup>

In addition, more employers — "nearly one third of large companies," as of 2016 — are covering gender reassignment as part of employee health benefit packages.<sup>17</sup>

Several federal courts, however, have declined to mandate coverage of gender reassignment surgery. One journal article summarized a 2001 case:

In Smith v. Rasmussen, the Eighth Circuit upheld Iowa's refusal to fund sex reassignment surgery, acknowledging that while the surgery "may be medically necessary in some cases," the "availability of other treatment options" for gender identity disorder and "lack of consensus in the medical community" about the efficacy of the surgery permits states to refuse coverage for the intervention under Medicaid. The appellate court also cited fiscal concerns as a valid reason to reject coverage of surgical interventions that facilitate transition.<sup>18</sup>

In a more recent 2014 case, the U.S. Court of Appeals for the First Circuit, in a 3-2 en banc decision, ruled that Massachusetts did *not* have to provide sex reassignment surgery ("SRS") to a prisoner. The ruling came after the court examined testimony from two expert witnesses for the state who "did not view SRS as medically necessary in light of 'the whole continuum from noninvasive to invasive' treatment options available."<sup>19</sup>

# **Federal Government Policy**

In the United States, the federal government (even under Obamacare) does not dictate all coverage decisions for the entire health care system. Nevertheless, it does operate a number of major health care

programs, so federal decisions on these issues are likely to be very influential upon other insurers. The largest federal health care program is Medicare, which provides health care to senior citizens.<sup>20</sup>

The federal government has gone through several stages in its evaluation of whether gender reassignment surgery is "medically necessary" for those receiving health coverage under Medicare.

#### 1989 National Coverage Decision

In 1989, the Health Care Financing Administration of the Department of Health and Human Services issued a "National Coverage Decision" (NCD, now referred to as a National Coverage Determination) explicitly *denying* coverage for "sex reassignment surgery." Here is the full text of that decision, with simple-language definitions of some of the medical terms inserted in brackets (not in the original):

#### TRANSSEXUAL SURGERY

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration [removal of the testicles], penectomy [removal of the penis] and vulva-vaginal construction [creation of an artificial vagina]. Surgery for the female-to-male transsexual consists of bilateral mammectomy [removal of both breasts], hysterectomy [removal of the uterus] and salpingo-oopherectomy [removal of the ovaries], which may be followed by phallosplasty [creation of an artificial penis] and the insertion of testicular prostheses [artificial testicles].

Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications of these surgical procedures. For these reasons, transsexual surgery is not covered.<sup>21</sup>

This stood as the federal government's official policy for 25 years, until 2014.

# 2014 HHS Appeals Board Decision

However, on May 30, 2014, in response to a complaint from a Medicare beneficiary who had been denied coverage for sex reassignment surgery, a Departmental Appeals Board of the Department of Health and Human Services overturned the 1989 decision. The Board claimed that it violated the "reasonableness standard" which requires that "the findings of fact, interpretations of law, and applications of fact to law ... are reasonable" based on the relevant evidence.<sup>22</sup>

After considering evidence used in making the original NCD, as well as more recent evidence submitted by the "aggrieved party," "six advocacy organizations" that participated as amici curiae, and several "expert witnesses," the Board concluded, "The NCD is invalid because a preponderance of the evidence in the record as a whole supports a conclusion that the NCD's stated bases for its blanket denial of coverage for transsexual surgery are not reasonable."<sup>23</sup>

The Board outlined the reasons for its conclusion, which included the following:

- "The new evidence indicates acceptance of criteria for diagnosing transsexualism."<sup>24</sup>
- "The new evidence indicates that transsexual surgery is safe."<sup>25</sup>
- "The new evidence indicates that transsexual surgery is an effective treatment option in appropriate cases."<sup>26</sup>
- "The new evidence indicates that the NCD's rationale for considering the surgery experimental is not valid."<sup>27</sup>

Although this decision (hereinafter cited as "2014 appellate decision") struck down the national policy that automatically excluded Medicare coverage of sex reassignment surgery, its effect was *not* to *require* such coverage nationwide. Instead, it left the question of coverage for sex reassignment surgery to be decided on a case-by-case basis. As the Board explained:

The decision does not bar CMS [the Centers for Medicare & Medicaid Services, successor to the Health Care Financing Administration] or its contractors from denying individual claims for payment for transsexual surgery for other reasons permitted by law. Nor does the decision address treatments for transsexualism other than transsexual surgery. The decision does not require CMS to revise the NCD or issue a new NCD, although CMS, of course, may choose to do so.<sup>28</sup>

#### 2016 CMS Decision Memo

From the point of view of transgender activists, the 2014 appellate decision was a victory – but an incomplete one. It still left open the possibility that some Medicare beneficiaries could end up being denied the surgery (now more commonly called "gender reassignment surgery") that they desire. What they wanted was a National Coverage Determination (NCD) *mandating* coverage of gender reassignment surgery on the grounds that it is a medically necessary treatment for those suffering from gender dysphoria. Many transgender activists may have believed that this was the logical next step – one that they could reasonably expect from the sympathetic Obama administration.

So they filed "a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria."<sup>29</sup> They must have been disappointed when, in 2016, the Centers for Medicare & Medicaid Services (CMS) issued a detailed Decision Memo (hereinafter cited as "2016 decision memo") *declining* to issue an NCD on this topic, "because *the clinical evidence is inconclusive*" (emphasis added).<sup>30</sup>

More specifically, CMS declared that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively" (emphasis added).<sup>31</sup>

It is worth examining more closely what CMS concluded about the inadequacy of the currently available evidence.

First, the CMS staff did an extensive search of the medical literature for studies focusing on the outcomes of gender reassignment surgery. While there is an abundance of literature on the general topic of such surgery, much of it involves individual case reports or details of specific surgical procedures – neither of which are helpful in determining the safety or effectiveness of such procedures for the general population of individuals suffering from gender dysphoria.

Instead, it was necessary to seek out studies that reported on "functional outcomes." Since the goal of gender reassignment surgery is to improve the patient's *mental* rather than physical health, these studies rely on "psychometric instruments" – defined as "scientific tools to measure individuals' mental capabilities and behavioral style." Such tools must demonstrate both "validity" ("how well the tool actually measures what it was designed to measure") and "reliability" ("how accurately results of the tool would be replicated" in identical research). The CMS description of why these concepts are important hints at the difficulty in establishing definitive evidence that such surgery is "medically necessary":

Reliability and validity are important because when evaluating patients with gender dysphoria *most of the variables of interest (e.g., satisfaction, anxiety, depression) are latent in nature (not directly observed but are rather inferred) and difficult to quantify objectively* (emphasis added).<sup>32</sup>

#### "All studies reviewed had potential methodological flaws . . . "

CMS ended up analyzing 33 studies, published between 1979 and 2015, that met their standards for inclusion. In evaluating the quality of these studies, CMS immediately noted one red flag: "There was a single randomized study."<sup>33</sup> The use of random samples — or in this case, random assignment to a group that would receive surgery or a group that would not — is generally considered one of the criteria for "gold standard" research, yet it is a technique that has almost never been used in studying the outcomes of gender reassignment surgery.

#### CMS concluded:

Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding ..., small sample sizes, lack of validated assessment tools, and considerable lost to follow-up (emphasis added).<sup>34</sup>

Not only were "the quality and strength of evidence" low, but the results were mixed:

Of the 33 studies reviewed, published results were conflicting – some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population. The majority of studies were non-longitudinal, exploratory type studies (i.e., in a preliminary state of investigation or hypothesis generating), or did not include concurrent controls or testing prior to and after surgery.<sup>35</sup>

CMS concluded that only a handful of the studies were even useful for their evaluation – and they showed little demonstrable benefit from gender reassignment surgery (GRS):

After careful assessment, we identified six studies that could provide useful information (Figure 1). Of these, the four best designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies *did not demonstrate clinically significant changes* or differences in psychometric test results after GRS (emphasis added).<sup>36</sup>

CMS also reported that only "[t]wo studies (three articles) assessed functional endpoints (request for surgical reassignment reversal and morbidity/mortality)," as opposed to assessing more subjective "quality of life" measures.

#### The Swedish Study

One of the studies that did assess "functional endpoints," conducted in Sweden, was perhaps the strongest study on the outcome of gender reassignment surgery. It is worth quoting the CMS summary of this study at length (emphasis added throughout):

Although the data are observational, they are robust because the Swedish national database is *comprehensive* (including all patients for which the government had paid for surgical services) and is notable for uniform criteria to qualify for treatment and financial coverage by the government. ...

Dhejne et al., (2011)<sup>37</sup> tracked all patients who had undergone reassignment surgery (mean age 35.1 years) over a 30 year interval and compared them to 6,480 matched controls. *The study identified increased mortality and psychiatric hospitalization compared to the matched controls. The mortality was primarily due to completed suicides (19.1-fold greater than in control Swedes), but death due to neoplasm and cardiovascular disease was increased 2 to 2.5 times as well.* We note, mortality from this patient population did not become apparent until after 10 years. *The risk for psychiatric disease (18%)*. The risk for attempted suicide was greater in male-to-female patients regardless of the gender of the control. Further, we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality.<sup>38</sup>

In this "robust" study, the consequences of gender reassignment surgery are startling, and appear to be uniformly negative. They encompass not only higher rates of mental illness (as indicated by psychiatric hospitalization) than in the general Swedish population, but higher rates of physical illness – cancer ("neoplasm") and heart disease – as well.

Most shocking of all, however, was the rate of completed suicides – which was over *19 times higher* than in the general Swedish population. Transgender activists often insist that the reason gender reassignment surgery is "medically necessary" is in order to *prevent* the suicides which might otherwise occur among those who identify as transgender but are frustrated in their desire to surgically alter their bodies. Yet the Swedish study shows that extraordinary rates of suicide persist *after* surgery.

Not only that, but the study "cannot exclude therapeutic interventions as a *cause* of the observed excess morbidity and mortality" (emphasis added). In other words, not only does gender reassignment surgery (and other "therapeutic interventions" such as hormone therapy) not demonstrably benefit those who identify as transgender – *it may actively harm them*. Not only are such interventions not "medically necessary" – they may be dangerous.

CMS also identified other weaknesses in the evidence, regarding "patient care" ("Few of the U.S.-based reassignment surgeons we could identify work as part of an integrated practice, and few provide the most complex procedures"<sup>39</sup>); "psychometric tools" ("Most instruments that were specific for gender dysphoria were designed by the investigators themselves or by other investigators within the field using limited populations and lacked well documented test characterization"); "generalizability" ("Most of these studies were conducted outside of the U.S. . . ."); and "knowledge gaps" ("The Institute of Medicine, the National Institutes of Health, and others also identified many of the gaps in the data"). <sup>40</sup>

#### **Other Sources**

The 2016 decision memo searched for other sources of data on the effectiveness of gender reassignment surgery – and found them to be sparse.

The search included "External Technology Assessments" and found:

There were no AHRQ [Agency for Healthcare Research and Quality] reviews on this topic.

There are no Blue Cross/Blue Shield Health Technology Assessments written on this topic within the last three years....

There were no National Institute for Health and Care Excellence (NICE) reviews/guidance documents on this topic.

They did find, "There was a technology assessment commissioned by the New Zealand Ministry of Health . . .," asking whether there was "evidence of effectiveness" for gender reassignment surgery (GRS) for "particular subgroups of people with transsexualism," and "what subgroups would benefit from GRS?" However, "The authors concluded that there was not enough evidence to answer either of the research questions."<sup>41</sup>

They examined "Evidence-Based Guidelines" and found:

ACOG [American College of Obstetricians and Gynecologists] did not have any evidence-based guidelines on this topic . . .

The American Psychiatric Association (APA) was unable to identify any Randomized Controlled Trials (RTCs) [sic] regarding mental health issues for transgender individuals.

The Endocrine Society published a "Clinical Practice Guideline" focused primarily on endocrine (i.e., hormone) treatment of those who identify as transgender, but including a section on surgery as well. However, they cautioned about the quality of evidence available:

This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low.<sup>42</sup>

As for "Pending Clinical Trials," they found the government clearinghouse website ClinicalTrials.gov reported that there is only one "currently listed and recently active trial directed at assessment of the clinical outcomes pertaining to individuals who have had gender reassignment surgery."<sup>43</sup>

# Comparing the 2014 Appeals Board Decision and the 2016 Decision Memo

On the one hand, the 2014 appellate decision by the Departmental Appeals Board and the 2016 decision memo by CMS both leave the actual *policy* regarding Medicare coverage of gender reassignment surgery in the same place – to be decided on a case-by-case basis without either a national coverage exclusion or a national coverage mandate.

On the other hand, these two decisions – only two years apart, and both by agencies of the U.S. Department of Health and Human Services (HHS) – are strikingly different in tone and seem to largely contradict each other, with the 2014 appellate decision offering the largely positive conclusion that "transsexual surgery is an effective treatment option," while the 2016 decision was much more cautious, concluding that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes."

How could these two bodies have arrived at such different conclusions, and which is likely to be more reliable? A careful examination suggests some answers.

### Authors

The first and most basic questions to be asked are, "Who were the authors of each decision? What were their qualifications?"

The 2014 appellate decision was signed by three members of the Departmental Appeals Board – Leslie A. Sussan, Constance B. Tobias, and Sheila Ann Hegy. All three are *attorneys* – none is a medical doctor or scientist.<sup>44</sup>

The 2016 CMS Decision Memo, on the other hand, was authored by a six-member team. Although two of them, Tamara Syrek Jensen and Linda Gousis, were also attorneys, three of the other members were medical doctors (Joseph Chin, MD, MS; James Rollins, MD, PhD; Elizabeth Koller, MD), and one, Katherine Szarama, has a Ph.D. in Medical Science.<sup>45</sup>

#### Sources

Another key question is, "What were their sources of information?"

One reason the Departmental Appeals Board in 2014 overturned the 1989 policy was because they said the latter was largely based on a single, 11-page report that the former National Center for Health Care Technology of the HHS Public Health Service had issued in 1981, titled "Evaluation of Transsexual Surgery."<sup>46</sup> The "NCD record" submitted by CMS in response to the appeal consisted largely of this lone report.

As new evidence, the AP ("aggrieved party") submitted written statements from four expert witnesses: Randi Ettner, PhD, a clinical psychologist; and three physicians, Katherine Hsiao, Marci L. Bowers, and Sherman N. Leis. The AP also submitted an appendix of at least thirty sources cited by Ettner. In addition, the Board accepted "requests by six advocacy organizations to participate as amici curiae." Briefs were submitted by the Human Rights Campaign (HRC, the leading LGBT activist organization) and the World Professional Association for Transgender Health (WPATH, the leading professional organization supporting and setting standards for gender transition). A joint brief was filed by the FORGE Transgender Aging Network, the National Center for Transgender Equality, the Sylvia Rivera Law Project, and the Transgender Law Center.<sup>47</sup> HRC submitted 62 exhibits with its brief.<sup>48</sup>

# Experts

All three of the physicians cited as "expert witnesses" – Hsiao, Bowers, and Leis – actually perform gender reassignment surgeries themselves. Hsiao, of San Francisco, "specializes in gender affirming hysterectomy as well as fertility and pelvic health for Transmen and the LGBTQ community."<sup>49</sup> Leis is an

osteopath who heads The Philadelphia Center for Transgender Surgery.<sup>50</sup> And Bowers, who practices in Burlingame, Calif., is a biological male who actually identifies as a transgender female, having been born as "Mark," married, and fathered three children before transitioning at the age of 38.<sup>51</sup> Bowers is also on the National Board of Directors of the Transgender Law Center.<sup>52</sup> Randi Ettner, although not a surgeon, also specializes in serving those who identify as transgender. She is on the Board of WPATH,<sup>53</sup> and she and her husband Frederic M. Ettner (a family physician) have endowed a "Fellowship in Transgender Health" in their own names at the University of Minnesota.<sup>54</sup>

All this suggests that these individuals are indeed experts in the techniques of gender transition and gender reassignment surgery — but hardly unbiased ones. As the Board conceded, the six groups that filed amicus briefs were "advocacy organizations," not scientific ones. And the four "experts" are also clearly activists in support of the transgender agenda as well. The three surgeons would stand to profit handsomely from an expansion of insurance coverage (including Medicare coverage) for gender reassignment surgery, so they had little incentive to draw the Board's attention to evidence that such surgery may *not* be "medically necessary."

# **CMS** Position

Oddly, the Centers for Medicare & Medicaid Services notified the Board that it "declines to submit a response" to the complaint. Yet at the same time, it stated that it "does not wish to reconsider the NCD" from 1989.<sup>55</sup>

Thus, the adjudication of the 2014 appeal resembled a lawsuit in which the defendant concedes no fault and declines to negotiate a settlement, yet at the same time simply mounts no defense. The only evidence presented to the Board (which included no doctors or scientists) was evidence supportive of gender reassignment surgery, submitted by ideologically driven activist organizations and "experts" with a vested interest in the continued practice (and expanded funding) of such surgeries. Under such circumstances, it is hardly surprising that the Board's ruling was favorable to the practice of gender reassignment surgery.

However, when faced with a request in 2016 to issue a *new* National Coverage Determination that would *mandate* Medicare coverage of gender reassignment surgery, the CMS response (for unknown reasons) was quite different. This time, the decision was made by a team that included people with medical and scientific expertise. This time, CMS undertook its own, independent search of the academic literature and its own evaluation of the evidence. And this time – under circumstances clearly more likely to result in a scientifically valid conclusion – the outcome was much *less* favorable toward gender reassignment surgery.

# **Studies Highlighted**

Although the Board in the 2014 appellate decision received at least 62 and possibly as many as 92 "exhibits" from the aggrieved party and the Human Rights Campaign,<sup>56</sup> in its written decision the Board provided, in a four-page attachment, "brief summaries of key findings" in only 13 of the studies submitted.<sup>57</sup> In contrast, CMS in its 2016 Decision Memo gave an overview of all 33 of the studies that met its inclusion criteria, taking up 33 pages in the PDF version of the Memo.<sup>58</sup>

Only seven of the thirteen studies summarized in the 2014 appellate decision were even among those that met the CMS inclusion criteria in the 2016 Decision Memo. Only *one* of the studies highlighted in

2014 was among the "four best designed and conducted studies" in 2016. These facts tend to suggest that the 2016 decision was more thoroughly researched and thus likely to be more reliable in its conclusions.

It is intriguing to compare the research summaries in the two documents. Although the 2014 appellate decision and the 2016 decision memo each included both positive and negative findings regarding the impact of gender reassignment surgery, there was a notable difference in tone, with the more thoroughly researched 2016 decision memo highlighting more of the negative findings of the research. Let's compare the descriptions of the seven studies summarized in both documents.

The bibliographical citations below are as they appear in the 2016 decision memo; the studies are presented in the chronological order of their publication.

Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex Behav. 1987 Dec;16 (6):511-22.

This 1987 study out of Germany surveyed subjects with gender identity issues before and after having hormone treatments. It then compared those who followed hormone therapy with surgery to those who delayed surgery.

The 2014 appellate decision reported only positive findings, implying that those who received surgery obtained benefits that were lacking for those who did not receive surgery:

[P]sychosocial adjustment of those who delayed surgery did not improve from the time of diagnosis to follow-up while statistically significant positive changes in gender role, sexual, and socioeconomic adjustment were seen in transsexuals who had had surgery.<sup>59</sup>

The 2016 decision memo gave a more nuanced view; for example, by noting that subjects were classified after hormone therapy on the basis of their continuing desire for gender reassignment surgery, with some having "unchanged desire," some "hesitant," and some by whom surgery was "no longer desired."

It noted, "Psychosocial adjustment scores were in the low end of the range with 'distinct difficulties' . . . at the initial evaluation" of all the subjects that desired surgery. Transgender activists might cite this as evidence of the urgency of the surgical treatment; however, it could just as easily be interpreted as demonstrating the need for psychological, *not* surgical, treatment.

The memo did indeed note improvement in the subjects who had surgery, saying, "Psychosocial adjustment scores were at the high end of the range 'few difficulties' . . . for the post-operative patients." However, the study also noted "few difficulties" for "the patients no longer wanting surgery." In other words, *overcoming* the desire for surgery was just as beneficial as indulging it – yet transgender activists are unwilling to invest any resources in accomplishing *that* goal.

The final intriguing finding noted in the 2016 decision memo was this:

[T]he post-operative patients had an additional test immediately prior to surgery. The first baseline score (19.7) would have characterized the patients as having "distinct difficulties" in psychosocial adjustment while the second baseline score (16.7) would have categorized the patients as having "few difficulties" in psychosocial adjustment despite the absence of any intervention except the prospect of having imminent reassignment surgery.<sup>60</sup>

In other words, those who had surgery did experience improvements in "psychosocial adjustment," but much of the improvement occurred *before* the surgery was actually performed – suggesting more of a placebo effect than any direct impact from the surgery itself. This would tend to undermine the argument that gender reassignment surgery is "medically necessary."

# Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.

This 1990 study out of the United Kingdom was the *only* one of the 33 studies evaluated in the 2016 decision memo that used a random sample, in the sense that individuals "who had qualified for male-to-female reassignment surgery" (no female-to-male subjects were included) were randomly assigned to either receive early surgery or undergo a more standard waiting period.

Again, the 2014 appellate decision reported only positive findings for this study:

Patients who received surgery were "seen to improve significantly as far as neurotic symptoms are concerned and to become more socially active" in comparison with the patients who had not yet received surgery.<sup>61</sup>

The 2016 decision memo, though, again points out the numerous psychological problems that often accompany gender dysphoria. It identifies the subjects collectively as experiencing "moderate symptoms" of "free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality." Individual patients had had "a history of attempted suicide," "psychiatric treatment for non-gender issues," and "first degree relatives with psychiatric histories." These suggest a greater need for psychological treatment instead of surgical treatment. In addition, the findings call into question whether transgender treatment is really effective in helping biological males become more feminine; although "Bem Sex Role Inventory femininity scores were slightly higher than masculinity scores ... [t]he scores did not change in either group over time."

# Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.

This 1997 study out of Sweden surveyed individuals who had received gender reassignment surgery concerning their satisfaction with the results, and compared those who had surgery during its early years (before 1986) with those who had it between 1986 and 1995.

The 2014 appellate decision highlighted improvements in surgical techniques and care during the later period:

The study found that after 1985 "the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment," [and] that "[m]odern surgical techniques can give good aesthetic and functional results."

However, it also cautioned that "[p]ersonal and social instability before operation correlated with an unsatisfactory outcome of sex reassignment."<sup>62</sup> This should raise a major red flag, since "personal and social instability" are so common in this population.

The 2016 decision memo actually documents some of the concerns raised by the post-operative subjects, such as being "dissatisfied with shape or size of the neo-phallus" in female-to-male subjects; and being only "moderately satisfied because of insufficient vaginal volume" in the case of male-to-female subjects. In recent years, the latter group would also have a "neo-clitoris" created, but some "reported no sensation or no sexual sensation."

In addition:

A total of nine (18%) patients had doubts about their sexual orientation; . . . The study found that two female-to-male patients and two male-to-female patients regretted their reassignment surgery and continued to live as the natal [birth] gender, and two patients attempted suicide.<sup>63</sup>

Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.

This 2005 study out of the Netherlands was the only one of the thirteen studies cited in the 2014 appellate decision that was also among "the four best designed and conducted studies that assessed quality of life before and after surgery" according to the 2016 decision memo.<sup>64</sup>

The study initially screened 325 adolescents and adults; post-surgical data was obtained from 126 adults.<sup>65</sup> The 2014 appellate decision reported the outcome in positive terms:

The study found that "[a]fter treatment the group was no longer gender dysphoric," had "improved in important areas of function, that 1-4 years after surgery, SR [sex reassignment] appeared therapeutic and beneficial . . . [and that] the vast majority expressed no regrets about their SR." The study further concluded "that sex reassignment is effective" . . .

However, the 2014 appellate decision did say the study cautioned:

[C]linicians need to be alert for non-homosexual male-to-females with unfavourable psychological functioning and physical appearance and inconsistent gender dysphoria reports, as these are risk factors for dropping out and poor post-operative results.<sup>66</sup>

This appears to be a reference to biological males who wish to become female despite the fact that they remain sexually attracted to females (and thus are "non-homosexual"), and despite the fact that they are quite masculine in appearance. These are what have been called "autogynephilic transsexuals," described by scholar J. Michael Bailey as "men erotically obsessed with the image of themselves as women."<sup>67</sup> The reference to "unfavourable . . . physical appearance" is also consistent with this, as Bailey has reported that "autogynephiles do not typically look or act very feminine."<sup>68</sup>

The 2016 decision memo included more data that raise the question of whether hormone therapy and gender reassignment surgery should automatically be considered the most logical course of action for someone with gender dysphoria. Of 325 persons screened for the study, 103 (32 percent) "never started hormone therapy," while 34 of the remaining 222 (15 percent) "discontinued hormone therapy" after having started it. The memo also reported aspects of dissatisfaction with the outcome of surgical procedures:

Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents . . . reported incomplete satisfaction with their mastectomy procedure. . . . Regarding vaginoplasty [creation of an artificial

vagina], 20 of 67 (29.8%) male-to-female respondents . . . reported incomplete satisfaction with their vaginoplasty.<sup>69</sup>

*Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. Arch Sex Behav. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)* 

As indicated by the title, this 2006 study focused on post-surgical complications as reported by patients.

The 2014 appellate decision emphasized the positive, reporting the study's findings that "[r]eports of significant surgical complications were uncommon," . . . and that "[o[n average, participants expressed high levels of satisfaction with nearly all of the specific physical and functional outcomes of SRS."

It did note, however, that "one third had urinary stream problems."70

The 2016 decision memo also went into much more detail about the complications experienced by some patients:

Happiness with sexual function and the reassignment surgery was reported to be lower when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life [QOL] was impaired when pain in the vagina or genitals was present.

Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past . . .<sup>71</sup>

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. J Sex Med. 2009 Mar;6(3):752-60. Epub 2008 Nov 17.

This 2009 study out of Belgium focused only on a sample of 50 "transsexual women" (that is, biological males who have had surgery to make their features appear like those of females).

Again, the 2014 appellate decision generally focused on the positive, quoting the study as finding that the "sample ... functions well after surgery on a physical, emotional, psychological and social level." However, the study also found that "with respect to sexuality ... transsexual women appear to suffer from specific difficulties, especially concerning arousal, lubrication and pain."<sup>72</sup>

The 2016 decision memo noted further that "two (4.0%) participants reported 'sometimes' regretting reassignment surgery and 23 (46.0%) were not in a relationship." The study also used a self-designed "visual analog scale (VAS)" to measure satisfaction with body traits and appearance, and the 2016 decision memo reported, "VAS scores of body image . . . were lowest for body hair, facial hair, and voice characteristics." The study also included a "Female Sexual Function Index (FSFI)," and "[t]he total FSFI score was 16.95 . . . out of a maximal 36," or less than half of the maximum score – although how that compares to the average woman is unclear, since "data on test population controls were not provided."<sup>73</sup>

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

This 2010 study of 42 subjects out of Sweden was unique in evaluating outcomes from the perspective of both patients and clinicians.

The 2014 appellate decision cited the study's positive conclusion:

[T]he outcome was very encouraging from both perspectives ... with almost 90% enjoying a stable or improved life situation at follow-up and only six out of 42 (according to the clinician) with a less favorable outcome.<sup>74</sup>

The 2016 decision memo explained that the study used a measure of well-being called the "Global Assessment of Functioning," or "GAF." The study findings seemed to suggest that subjective reports of improvement from patients themselves should be taken with a grain of salt, since "95.2% of all enrolled patients self-reported improvement in GAF, [yet] in contrast, clinicians determined GAF improved in 61.9% of patients. Clinicians observed improvement in . . . 72% of male-to-female patients," but in less than half (47%) of female-to-male patients. Only a minority of all patients (42.9%) experienced improvement on a scale that was considered "significant" according to a pre-specified standard. In addition, "11.9% were currently being treated with anti-depressants or tranquilizers."

In another striking finding (albeit one with a tiny sample size), it was reported that of the five patients who had *discontinued* the reassignment process, *all five* "were rated by clinicians as having improved."<sup>75</sup> This offers a tantalizing hint that when those who suffer from gender dysphoria seek an alternative to gender reassignment, they may actually have the best chance of improvement.

# Conclusion

This paper is not a comprehensive, original review of the evidence regarding the medical necessity of gender reassignment surgery. However, the burden of proof must rest upon those who argue that such procedures *are* "medically necessary." This is particularly true under the unusual circumstance whereby a *surgical* solution is proposed for a *psychological* problem.

The two documents described in this paper – the 2014 HHS Appeals Board Decision, and the 2016 CMS Decision Memo – appeared to reach quite different conclusions (although both have the effect of allowing gender reassignment surgery to be deemed "medically necessary" on a case-by-case basis). It is also important to note that they examined *only* gender reassignment surgery – not hormone therapy or any other "transition-related" medical care. In addition, technically they were only responsible for examining the question of surgery for the Medicare-eligible population, which is not the same as the entire population (although few if any of the studies examined appear to have made specific distinctions among adults based on age).

However, for reasons cited in the text, the 2016 decision memo appears to be the more reliable of the two. The 2014 appellate decision was produced by three lawyers with input from only transgender-affirming experts and amicus briefs. In 2014, the Centers for Medicare & Medicaid Services declined to provide a substantive defense of their 1989 National Coverage Decision.

The 2016 decision memo, on the other hand, was produced by a team dominated by medical experts. They conducted what may have been the most thorough and rigorous review of the medical literature on this topic ever undertaken, analyzing 33 studies published over 36 years.

The conclusion in the 2016 decision memo that "there is not enough high-quality evidence to determine whether gender reassignment surgery improves health outcomes" appears to indicate that the case for declaring such surgery to be "medically necessary" clearly remains unproven.

Peter Sprigg is a Senior Fellow for Policy Studies at Family Research Council in Washington, D.C.

<sup>&</sup>lt;sup>1</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5);* (Arlington, VA: American Psychiatric Association, 2013), 830.

<sup>&</sup>lt;sup>2</sup> The only exception was phalloplasty (creation of an artificial penis), which had been obtained by only two percent and was desired by only an additional 27 pecent of biological females who identify as male. Jaime M. Grant, Lisa A. Mottet, Justin Tanis, Jack Harrison, Jody L. Herman, and Mara Keisling, "Injustice at Every Turn: A Report of the National Transgender Discrimination Survey," National Center for Transgender Equality and National Gay and Lesbian Task Force, 2011, 79,

http://www.thetaskforce.org/static\_html/downloads/reports/reports/ntds\_full.pdf. <sup>3</sup> Ibid., 77.

<sup>&</sup>lt;sup>4</sup> "Cosmetic Surgery vs. Plastic Surgery," American Board of Cosmetic Surgery, accessed October 25, 2017, <u>https://www.americanboardcosmeticsurgery.org/patient-resources/cosmetic-surgery-vs-plastic-surgery/</u>.

<sup>&</sup>lt;sup>5</sup> "Cosmetic Procedures," American Society of Plastic Surgeons, accessed October 25, 2017,

https://www.plasticsurgery.org/cosmetic-procedures.

<sup>&</sup>lt;sup>6</sup> Gender reassignment surgery is not the same as surgery for an "intersex" condition, in which there is a biological disorder of sexual development which may result in anatomical characteristics that are atypical.

 <sup>&</sup>lt;sup>7</sup> "Glossary – M," Medicare.gov, accessed November 14, 2017, <u>https://www.medicare.gov/glossary/m.html</u>.
<sup>8</sup> Again, in distinction from "intersex" conditions.

<sup>9</sup> DSM-5, 822.

<sup>&</sup>lt;sup>10</sup> Daphna Stroumsa, "The State of Transgender Health Care: Policy, Law, and Medical Frameworks," *American Journal of Public Health* 104 (2014): e36, accessed November 14, 2017,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953767/pdf/AJPH.2013.301789.pdf; citing American Psychiatric Association, *Highlights of Changes from DSM-IV-TR to DSM-5*, (APA, 2013).

<sup>&</sup>lt;sup>11</sup> "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.," World Professional Association for Transgender Health (WPATH), December 21, 2016,

http://www.wpath.org/site\_page.cfm?pk\_association\_webpage\_menu=1352&pk\_association\_webpage=3947.

<sup>&</sup>lt;sup>12</sup> Admittedly, the issue is somewhat different in Canada than it is in the U.S. This is due to Canada's single-payer health care system, under which the power of the national government to make health care decisions is greatly magnified.

<sup>&</sup>lt;sup>13</sup> Roger Collier, "Medically necessary: Who should decide?" *CMAJ* (Canadian Medical Association) 184 (2012): 1770-71, <u>http://pubmedcentralcanada.ca/pmcc/articles/PMC3494349/pdf/1841770.pdf</u>.

<sup>&</sup>lt;sup>14</sup> David Goldhill, "Who Defines 'Medical Necessity'?" *The Atlantic*, January 8, 2014, accessed November 14, 2017, <u>https://www.theatlantic.com/health/archive/2014/01/who-defines-medical-necessity/282500/</u>.

<sup>&</sup>lt;sup>15</sup> John Riley, "Minnesota's transgender surgery ban is unconstitutional, judge rules," *MetroWeekly*, November 16, 2016, accessed November 14, 2017,

http://www.metroweekly.com/2016/11/minnesotas-transgender-surgery-ban-unconstitutional/.

<sup>&</sup>lt;sup>16</sup> "Convicted killer gets sex-reassignment surgery on taxpayer's dime," Associated Press, January 8, 2017, accessed November 14, 2017, <u>http://abc13.com/news/prisoner-receives-gender-reassignment-surgery/1692155/</u>.

<sup>&</sup>lt;sup>17</sup> Bruce Japsen, "More Employers Cover Transgender Surgery As Politics Shift," *Forbes*, May 17, 2016, accessed November 14, 2017,

https://www.forbes.com/sites/brucejapsen/2016/05/17/as-transgender-politics-shift-more-employers-cover-gender-surgery/#5fd0c3b410db.

<sup>22</sup> "Decision: NCD 140.3, Transsexual Surgery" Department of Health and Human Services, Departmental Appeals Board, Appellate Division (Docket No. A-13-87, Decision No. 2576), May 30, 2014, 7,

https://www.hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf. <sup>23</sup> Ibid.

<sup>24</sup> Ibid., 9.

<sup>25</sup> Ibid., 11.

<sup>26</sup> Ibid., 15.

<sup>27</sup> Ibid., 21.

<sup>28</sup> Ibid., 1.

<sup>29</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," Centers for Medicare & Medicaid Services, August 30, 2016, accessed November 14, 2017, 2,

https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282.

<sup>30</sup> Ibid., 65.

<sup>31</sup> Ibid.

<sup>32</sup> Ibid., 8.

<sup>33</sup> Ibid., 10.

<sup>34</sup> Ibid., 62.

<sup>35</sup> Ibid.

<sup>36</sup> Ibid.

<sup>37</sup> Cecilia Dhejne, et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS ONE* 6 (2011), accessed November 14, 2017,

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885.

<sup>38</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 62.

<sup>39</sup> Ibid., 63.

<sup>40</sup> Ibid., 64.

<sup>41</sup> Ibid., 42-44.

<sup>42</sup> Ibid., 44-46.

<sup>43</sup> Ibid., 49.

<sup>44</sup> "Who are the Board Members & Judges?" Department of Health and Human Services, April 21, 2017, accessed November 14, 2017,

https://www.hhs.gov/about/agencies/dab/about-dab/who-are-the-board-members-and-judges/index.html. <sup>45</sup> "Katherine B. Szarama PhD, Presidential Management Fellow, CMS," LinkedIn, accessed November 14, 2017, https://www.linkedin.com/in/katherine-b-szarama-phd-627a172b/.

<sup>46</sup> "Decision: NCD 140.3, Transsexual Surgery," 4-5.

<sup>47</sup> Ibid., 5.

<sup>48</sup> Ibid., 6.

<sup>49</sup> "Katherine Hsiao, MD, FACOG," The San Francisco Transgender Institute, accessed July 25, 2017, http://sftrans.org/hsiao.

<sup>50</sup> "Dr. Sherman Leis," The Philadelphia Center for Transgender Surgery, accessed July 25, 2017,

http://www.thetransgendercenter.com/index.php/our-center/dr-leis-biography.html.

<sup>51</sup> "Top transgender surgeon has practice in Burlingame," ABC 7 News, April 24, 2015, accessed November 14, 2017,

http://abc7news.com/health/top-transgender-surgeon-has-practice-in-burlingame/680267/. <sup>52</sup> "Dr. Bowers' Curriculum Vitae," Marci L. Bowers, M.D., accessed November 14, 2017, http://marcibowers.com/dr-bowers/bowers-cv/.

<sup>53</sup> "About Dr. Ettner," RandiEttner.com, accessed July 25, 2017, <u>http://randiettner.com/#About</u>.

<sup>&</sup>lt;sup>18</sup> Liza Khan, "Transgender Health at the Crossroads: Legal Norms, Insurance Markets, and the Threat of Healthcare Reform," *Yale Journal of Health Policy, Law & Ethics* (2011): 399-400.

<sup>&</sup>lt;sup>19</sup> Kosilek v. Spencer, 774 F.3d 63 (1st Cir. 2014).

<sup>&</sup>lt;sup>20</sup> "CMS press toolkit," Centers for Medicare & Medicaid Services, May 17, 2013, accessed November 14, 2017, https://www.cms.gov/Newsroom/PressToolkit.html.

<sup>&</sup>lt;sup>21</sup> Health Care Financing Administration, "Medicare Programs; National Coverage Decisions," *Federal Register* Vol. 54, No. 160, August 21, 1989, 34572.

<sup>56</sup> It is unclear whether or how much the 30 submissions by the AP and the 62 submissions by HRC may have overlapped.

- <sup>57</sup> "Overview of the Scientific Literature in the New Evidence," Attachment to Decision No. 2576.
- <sup>58</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 10-42.
- <sup>59</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 2.
- <sup>60</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 35-36.
- <sup>61</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 3.
- 62 Ibid., Attachment, 1.
- <sup>63</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 20.
- <sup>64</sup> Ibid., 62.
- 65 Ibid., 39-40.
- <sup>66</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 4.
- <sup>67</sup> J. Michael Bailey, *The Man Who Would Be Queen: The Science of Gender-Bending and Transsexualism* (Washington: Joseph Henry Press, 2003), 146.

68 Ibid., 168.

- <sup>69</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 39-40.
- <sup>70</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 3.
- <sup>71</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 21.
- <sup>72</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 4.
- <sup>73</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 23-24.
- <sup>74</sup> "Decision: NCD 140.3, Transsexual Surgery," Attachment, 2.
- <sup>75</sup> "Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)," 15-16.

<sup>&</sup>lt;sup>54</sup> "Randi and Fred Ettner Fellowship in Transgender Health," University of Minnesota, accessed July 21, 2017, <u>https://www.sexualhealth.umn.edu/education-and-training/fellowships/randi-and-fred-ettner-fellowship-transgender-health</u>.

<sup>&</sup>lt;sup>55</sup> "Decision: NCD 140.3, Transsexual Surgery," 6.