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September 29, 2014

The Honorable Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 337H Humphrey Building
Washington, DC 20201

Dear Administrator Tavenner:

We write to express our significant concerns with the Centers for Medicare & Medicaid Services' (CMS) proposed Rule CMS -1614-P that would eliminate any and future coverage for bone conduction hearing devices that require medical diagnosis, a treatment plan formulated by a physician, and a prescription. Adoption of this proposal would mean that Medicare beneficiaries no longer would have access to the only hearing solutions designed to treat patients suffering from conductive or mixed hearing loss or single sided deafness.

In 2006, CMS began covering osseointegrated implants as prosthetics that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. Since 2006, new bone conduction hearing devices have been developed that are functionally similar to osseointegrated implants. However, rather than developing a principled means for evaluating coverage for these newer technologies to encourage and reward innovation, CMS has proposed a rule that has the effect of taking a huge step backwards – by not only denying access to Medicare coverage for these new technologies, but affirmatively reversing the coverage for devices that has been in place since 2006. The proposed policy will have a profound impact on Medicare beneficiaries who have no other solution to treat their hearing loss.

Unlike hearing aids, bone conduction hearing devices do not rely on amplification of sound, do not provide traditional "aid" to hearing, and do not rely on a functioning ear to transmit sound. Another key differentiator is that bone conduction hearing devices cannot be self-selected by patients, but instead require a physician prescription and a medical intervention by a specialized physician.

While the proposed rule correctly does not take away coverage for hearing solutions used to treat Medicare beneficiaries with sensorineural hearing loss (cochlear implants and brain stem implants), it would eliminate coverage for solutions for beneficiaries who suffer from mixed or conductive hearing loss or single sided deafness. In enacting the hearing aid exemption, Congress did not intend to single out this small beneficiary population as not deserving of covered medical treatment.

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We strongly urge CMS not to finalize its proposal and instead provide coverage for bone conduction hearing device technologies based on the following principles:

1) Patients with conductive hearing loss, mixed hearing loss and single sided deafness should have a covered benefit for treatment with a prosthetic.
2) Devices with the following characteristics should be considered hearing prosthetics: (a) replace all or part of the function of the ear, (b) restore hearing without amplifying sound waves, and (c) provide mechanical energy to one or both cochlea by transmission of the energy through the bone.
3) Proper use of prosthetics follows a medical/surgical model which requires a diagnosis and treatment plan. Therefore, coverage of a prosthetic should include a requirement that the device be available only upon a physician prescription and only for conditions where a hearing aid cannot provide a clinical benefit or is medically inappropriate.
4) Hearing aids are not prosthetics in that they amplify sound through the existing anatomy, rather than replacing part of the anatomy. Hearing aids do not require medical or surgical intervention and can be self-selected by individuals.

This approach draws a balance between providing Medicare beneficiaries access to medically necessary technology that cannot be treated through traditional self-selecting methods. We urge CMS not to finalize its proposal and instead allow for coverage of currently covered devices and promote a path forward for coverage of new bone conduction devices based on the principles above.

Sincerely,

Michael F. Bennet
United States Senator

United States Senate
WASHINGTON, DC 20510

October 2, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Administrator Tavenner:

We write to you today to express our concern with the Centers for Medicare & Medicaid Services' (CMS) proposal to reclassify Auditory Osseointegrated Implants (AOIs) as hearing aids. This policy would eliminate existing coverage for Medicare beneficiaries who have no other alternative to address their hearing loss for which these implants were developed. Additionally, this policy change would eliminate coverage for aftercare services for existing Medicare patients who have already had an AOI implanted to address their hearing loss.

As you know, Auditory Osseointegrated Implants are surgically implanted into the mastoid bone, and sound can then be transmitted through bones in the skull to a functioning cochlea. There are specific conditions where the function of the external and/or middle ear is impeded by anatomical deformities and cannot be ameliorated by amplification provided by hearing aids. Often, conventional hearing aids have been unsuccessful due to poor outcomes (constant feedback, occlusion, inability to maintain appropriate pressure on the mastoid for appropriate conduction) or the inability of the patient to tolerate (pressure ulcers, headaches, slippage), and there is no other option than seeking to use an AOI. It is estimated that the covered cost of such devices, surgery, and hospital fees is upwards of $12,000, and that this cost to a patient with hearing loss would likely double if insurance coverage were unavailable.

As these AOIs serve a unique set of patient needs that are not addressed by hearing aids, it is critical that CMS not reverse its current position that such devices are covered for patients who need them. We also believe that nothing has changed technically in relation to these devices to justify CMS reclassifying them as hearing aids, and that such a decision will undoubtedly lead to a dramatic reduction in the number of people who can afford such treatment. As an obvious result, many people who would otherwise address their hearing loss will have no affordable alternative and will continue to live with serious hearing loss issues. In addition to the obvious social and interpersonal difficulties that will result, studies indicate that failure to treat hearing loss is linked to increased symptoms of depression, a greater risk for falling, and an increased incidence of dementia. These are all significant issues for the Medicare population.

We recognize that CMS cannot provide coverage for hearing aids based on statutory limitations, but we urge you not to reclassify devices that you have already determined are not hearing aids as such. Otherwise, such devices and treatments will be unaffordable for many people who have no other option. We respectfully ask you to reconsider your proposal to reclassify Auditory Osseointegrated Implants as hearing aids.

Sincerely,

DEAN HELLER
U.S. Senator

BARBARA MIKULSKI
U.S. Senator

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ENVIRONMENT AND THE ECONOMY

September 2, 2014

Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Administrator Tavenner:

On July 11, 2014, the Centers for Medicare & Medicaid Services' (CMS) published Proposed Rule CMS-1614-P, which would eliminate Medicare coverage for prosthetic Auditory Osseointegrated Implants ("AOIs") that has been in place since 2006. As a Member of the House Energy and Commerce Committee which has jurisdiction over CMS, a hearing impaired American with a cochlear implant, and a grandfather of a child with an AOI, I strongly object to this proposal.

Contrary to what is stated in the Proposed Rule, AOIs are not hearing aids and are not covered by the hearing aid exclusion under Medicare. Neither the statute nor its legislative history support the broad interpretation CMS seeks in order to prohibit AOIs under the hearing aid exclusion. CMS has erroneously based the Proposed Rule upon an expansive and unsupported extension of the hearing aid exclusion, codified at 42 U.S.C. § 1862(a)(7) and 42 CFR § 411.15(d)(1), to include: "all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea." There is nothing in either the statute or the legislative history that would support this broad interpretation.

The statutory language under 42 U.S.C. § 1862(a)(7) of the exclusion refers only to "hearing aids or examinations therefor" – there is no reference to implantable hearing devices, middle ear implants, osseointegrated devices, or dental anchored bone conduction devices as none existed in 1965 when the Social Security Act was passed. At that time, patients could self-select available hearing aids, the same way they could with over-the-counter drugs. No physician order was required, nor was there any surgical intervention to implant the devices. Patients were accustomed to paying for these items out of pocket, as they did with other routine items and services covered by the exclusion (such as eyeglasses). Thus, the statute provides no support for the expansive interpretation of hearing aids set forth in the Proposed Rule.

Additionally, the legislative history underlying the statute does not suggest the broad reading used to justify the Proposed Rule. Again, a review of the published House and Senate reports

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refer only to excluding coverage for hearing aids and related examinations therefor, which must be considered in light of technology available at the time.

Indeed, the majority of the technologies that would be considered "hearing aids" under the Proposed Rule's expansive interpretation were not available (and many were not even in development) in 1965. In particular, AOIs simply could not have been contemplated by Congress at the time the hearing aid exception was enacted, because they did not exist.

The first AOI surgery did not occur until 1977 (in Sweden) - twelve years after the Act was passed. The first AOI (the Baha Implant System) was not approved by the Food and Drug Administration until 1995 – thirty years after the Act was passed. It defies reason to suggest that Congress in 1965 intended to exclude a technology that was not available until over a decade after statutory enactment.

When we look back to what was available for the hearing impaired in 1965, there were "bone conduction" hearing aids, however they bear no resemblance to the AOIs of today. Bone conduction hearing aids in 1965 consisted of an external sound processor fitted tightly around the head with a strap (often metal). These devices did not require or involve any surgical intervention and were not permanently affixed to the head. These types of bone conduction hearing aids are infrequently used with patients, primarily because of complications such as skin irritation and the availability of superior technology (AOIs). These devices most resemble today's Baha softband and Ponto softband, which consist of sound processors worn on an elastic band, primarily by children who are less than 5 years of age and therefore do not meet FDA indications for implantation with an AOI. Like bone conduction hearing aids, Baha softbands and Ponto softbands are not covered by Medicare under the current coverage language, since they do not involve any osseointegrated component.

In short, neither the statutory language codifying the hearing aid exclusion nor their underlying legislative histories support the Proposed Rule's broad interpretation of the exclusion. There are no parallels to draw between the hearing aids that existed in 1965 (or the functionality of the hearing aids that existed at that time) and AOIs that would support treating AOIs as hearing aids excluded under the Act.

It is also key to note that AOIs do not share the same design as hearing aids and also differ in terms of how they function. For example, a hearing aid consists of a microphone (to gather sound), an amplifier and a speaker (to deliver sound to the ear). Its function, as defined by the FDA, is that of a "wearable sound-amplifying device that is intended to compensate for impaired hearing." Such definitions highlight the distinct differences between AOIs and hearing aids. AOIs do not merely amplify signals, but transduce sound into mechanical vibrations. The inputted vibrations directly stimulate the cochlea. Secondly, AOIs have no speaker. Rather, the AOI delivers auditory inputs by transducing sounds into vibrations directly transmitted to the temporal bone. Further, AOIs cannot be self-selected by a patient as is the case with air conduction and bone conduction hearing aids. Instead, the selection of AOIs is contingent on medical necessity as judged and managed by a physician who must consider other treatment alternatives, and surgically implant the AOI if that treatment strategy is deemed necessary.

The Proposed Rule itself recognizes the inherent differences between hearing aids and AOIs, stating that "we [CMS] consider that a hearing aid provides assistance or 'aid' to hearing that already exists via a functioning ear." (Federal Register/Vol. 79, No. 133 (July 11, 2014) p. 40295.) Patients who receive AOIs do not have functioning ears. Instead, they require AOIs, which bypass and replace non-functioning or malfunctioning parts of the ear. While hearing aids amplify sound through the normal hearing pathway (from the outer ear, through the bones of the middle ear, to the cochlea and onto the auditory nerve), patients using AOIs receive sound directly from their implant system to the cochlea, bypassing the outer and middle ear entirely. These differences in design and functionality lend further support to the argument that the hearing aid exclusion does not extend to AOIs.

CMS is incorrect to maintain that AOIs are not prosthetics as they replace all or part of the ear - an internal body organ. CMS recognized as much in 2005, when it correctly determined that osseointegrated implants met the definition of prosthetics and began covering such devices for Medicare patients in 2006. Certain bone anchored hearing devices that replace the function of the outer, middle and/or inner ear clearly qualify as covered prosthetic devices as that phrase is defined in the Social Security Act:

> "prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens" (42 U.S.C. § 1861(s)(8))

By this definition it is clear that CMS is incorrect in its conclusion that AOIs are not a prosthesis as they replace all or part of an organ – the outer and middle ear. These devices operate by transducing sound into mechanical vibrations, which replace the function of the non-functioning or malfunctioning outer, middle or inner ear, entirely bypassing those portions of the hearing pathway and transmitting sound directly to the cochlea. The ear is a hearing organ is made up of three parts and non-function or malfunction in any one of these three parts typically renders a person unable to hear. Traditional hearing aids do not compensate for or overcome this non-function or malfunction and cannot restore this loss of hearing. By contrast, AOIs do replace the ear canal and/or middle ear – two internal organ systems within the organ of hearing for patients with conductive and mixed hearing losses. Taking away coverage for patients who have mixed or conductive loss effectively condemns these patients to deafness, since these patients cannot wear or benefit from hearing aid because of congenital defects or chronic diseases.

AOIs are also an effective treatment and meet the requirements of a prosthetic for patients with severe to profound hearing loss in only one ear. For these patients, the implant replaces the inner ear (the cochlea) of the deafened ear, transmitting sound to the opposite cochlea and allowing the patient to hear. To reiterate, AOIs *replace* the non-functioning, diseased, or absent ear canal and the middle ear in patients with conductive and mixed hearing loss. For patients with single-sided deafness, an AOI replaces the malfunctioning cochlea and redirects sound from the non-functioning (deafened) ear directly to the cochlea of the ear with hearing.

One particularly troubling aspect of the Proposed Rule is that it completely reverses CMS's own position on AOIs, which since 2006 have been covered by Medicare as prosthetics. Specifically, effective January 1, 2006, CMS modified the Medicare Benefit Policy Manual to specifically carve out osseointegrated devices from the definition of hearing aids, stating:

> Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.
>
> The following are prosthetic devices . . .
>
> Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. (CMS 100 - Hearing Aids and Auditory Implants (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05).)

There is no basis for CMS's reversal of its prior position; AOIs function precisely the same way they did in 2006 when CMS correctly recognized that these devices were prosthetics that replaced the function of the middle ear. Osseointegrated devices are surgically implanted by specially trained physicians in circumstances where hearing aids are medically inappropriate and cannot be utilized. Having originally concluded that AOIs are prosthetics and covering these osseintegrated implants over the past eight years, CMS sets a dangerous precedent for patients, health care providers and industry by reversing course on a treatment solution that has proven effective for more than 40,000 patients in the US (and that is supported by over 300 published articles). If the Proposed Rule is adopted, the United States would be one of the very few industrialized nations not to cover osseointegrated implants. Also troubling, Medicare beneficiaries will be denied access to new hearing technologies in the future as CMS's action will have a chilling effect on investment in new innovations.

Of course CMS needs to be mindful of cost containment in the Medicare System. However, there are effective ways for CMS to evaluate new technologies without opening the coverage floodgates and without leaving patients without an effective solution to treat their hearing loss. CMS must maintain coverage for brain stem implants, cochlear implants, and osseointegrated implants as prosthetics, and to work with the experts in the field (health care professional societies and organizations and industry) to develop an effective process for evaluating new technologies.

We thank you for your attention to this critical matter.

Sincerely,

David B. McKinley, P.E.

United States Senate
WASHINGTON, DC 20510

October 2, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Administrator Tavenner:

We write to you today to express our concern with the Centers for Medicare & Medicaid Services' (CMS) proposal to reclassify Auditory Osseointegrated Implants (AOIs) as hearing aids. This policy would eliminate existing coverage for Medicare beneficiaries who have no other alternative to address their hearing loss for which these implants were developed. Additionally, this policy change would eliminate coverage for aftercare services for existing Medicare patients who have already had an AOI implanted to address their hearing loss.

As you know, Auditory Osseointegrated Implants are surgically implanted into the mastoid bone, and sound can then be transmitted through bones in the skull to a functioning cochlea. There are specific conditions where the function of the external and/or middle ear is impeded by anatomical deformities and cannot be ameliorated by amplification provided by hearing aids. Often, conventional hearing aids have been unsuccessful due to poor outcomes (constant feedback, occlusion, inability to maintain appropriate pressure on the mastoid for appropriate conduction) or the inability of the patient to tolerate (pressure ulcers, headaches, slippage), and there is no other option than seeking to use an AOI. It is estimated that the covered cost of such devices, surgery, and hospital fees is upwards of $12,000, and that this cost to a patient with hearing loss would likely double if insurance coverage were unavailable.

As these AOIs serve a unique set of patient needs that are not addressed by hearing aids, it is critical that CMS not reverse its current position that such devices are covered for patients who need them. We also believe that nothing has changed technically in relation to these devices to justify CMS reclassifying them as hearing aids, and that such a decision will undoubtedly lead to a dramatic reduction in the number of people who can afford such treatment. As an obvious result, many people who would otherwise address their hearing loss will have no affordable alternative and will continue to live with serious hearing loss issues. In addition to the obvious social and interpersonal difficulties that will result, studies indicate that failure to treat hearing loss is linked to increased symptoms of depression, a greater risk for falling, and an increased incidence of dementia. These are all significant issues for the Medicare population.

We recognize that CMS cannot provide coverage for hearing aids based on statutory limitations, but we urge you not to reclassify devices that you have already determined are not hearing aids as such. Otherwise, such devices and treatments will be unaffordable for many people who have no other option. We respectfully ask you to reconsider your proposal to reclassify Auditory Osseointegrated Implants as hearing aids.

Sincerely,

DEAN HELLER
U.S. Senator

BARBARA MIKULSKI
U.S. Senator

Congress of the United States
Washington, DC 20515

September 16, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1614-P
PO Box 8013
Baltimore, MD 21244-1850

Dear Administrator Tavenner,

As members of Congress who support hearing health, we are alarmed that CMS has proposed to reclassify Auditory Osseointegrated Implants (AOI) as hearing aids, which would reverse a CMS coverage policy that was developed and applied in 2006. Your proposal to existing regulation §411.15(d)(1) would result in the elimination of existing Medicare coverage for such implants since hearing aids are excluded from Medicare coverage by statute. This would have the effect of barring future coverage, and in many cases treatment, for people who have no alternative to addressing the types of hearing loss for which these implants were developed and consequently approved by CMS for coverage. In addition, such a change would eliminate coverage for aftercare services for existing Medicare patients who have already had an AOI implanted to address their hearing loss.

As you are aware, Auditory Osseointegrated Implants are surgically implanted into the mastoid bone, and sound can then be transmitted through bones in the skull to a functioning cochlea. There are specific conditions where the function of the external and/or middle ear is impeded by anatomical deformities and cannot be ameliorated by amplification. Often conventional hearing aids have been unsuccessful due to poor outcomes (constant feedback, occlusion, inability to maintain appropriate pressure on the mastoid for appropriate conduction) or the inability of the patient to tolerate (pressure ulcers, headaches, slippage), and there is no other option than seeking to use an AOI. It is estimated that the covered cost of such devices, surgery and hospital fees is upwards of $12,000, and that this cost to the person with hearing loss would likely double if insurance coverage were unavailable.

We believe it is critical that CMS not reverse its current position that such devices are covered for people who need them. We also believe that nothing has changed technically in relation to these devices to justify CMS reclassifying them as hearing aids, and that such a decision will undoubtedly lead to a dramatic reduction in the number of people who can afford such treatment. As an obvious result, many people who would otherwise address their hearing loss will have no affordable alternative and will continue to live with serious hearing loss issues. In addition to the obvious social and interpersonal difficulties that will result, studies indicate that failure to treat hearing loss is linked to increased symptoms of depression, a greater risk for falling, and an increased incidence of dementia. These are all significant issues for the Medicare population.

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Although we understand that CMS cannot provide coverage for hearing aids based on statutory limitations, we urge you not to reclassify devices that you have already determined are not hearing aids as such. Otherwise, such devices and treatments will be unaffordable for many people who have no other option.

We respectfully ask you, therefore, to reconsider your proposal to reclassify Auditory Osseointegrated Implants as hearing aids

Sincerely,

TOM LATHAM
Member of Congress
Co-Chair, Hearing Health Caucus

CAROLYN McCARTHY
Member of Congress
Co-Chair, Hearing Health Caucus

DAVID B. McKINLEY, P.E.
Member of Congress
Member, Hearing Health Caucus

MIKE THOMPSON
Member of Congress
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PATRICK J. TIBERI
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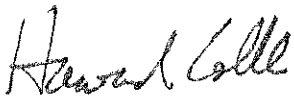
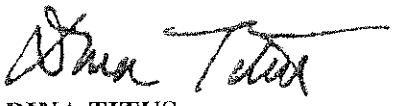
PETER J. ROSKAM
Member of Congress



HOWARD COBLE
Member of Congress

ELIZABETH H. ESTY
Member of Congress

STEVE STOCKMAN
Member of Congress



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Member of Congress

PETE OLSON
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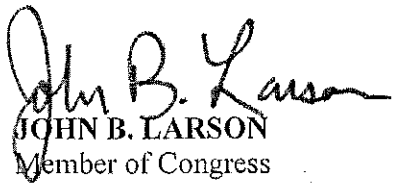

JOHN B. LARSON
Member of Congress

LEE TERRY
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Member of Congress

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DAVID W. JOLLY
Member of Congress