



OUR MISSION:

To advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness.

September 8, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1751-P; Medicare Program; CY 2022 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 23, 2021) (“2022 PFS Proposed Rule” or “Proposed Rule”)

Dear Administrator Brooks-LaSure:

On behalf of the American Cochlear Implant Alliance (ACI Alliance), I thank you for the opportunity to provide comments on the 2022 PFS Proposed Rule, *CY 2022 (ACI Alliance) Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies* (the Proposed Rule) [CMS-1751-P]. The ACI Alliance is a non-profit organization with the mission to address barriers to cochlear implantation by sponsoring research, driving heightened awareness and advocating for improved access to cochlear implants for patients of all ages across the United States. ACI Alliance members are hearing care clinicians including surgeons, audiologists, speech-language pathologists (SLPs) as well as scientists, educators, adults with hearing loss, and family members.

The proposals described in the Proposed Rule, if adopted without change, would reduce Medicare payment for critical cochlear implant reprogramming services performed in non-facility settings by about 10% for certain reprogramming services and by almost 14% for electrocochleography services. While some of this proposed payment reduction is attributable to the conversion factor reduction necessitated by budget neutrality provisions of the Medicare Act, the majority of the reduction is attributable to the impact of CMS’ proposal to update the non-physician clinical labor rates.

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As CMS itself notes, the update of clinical labor rates would have a disproportionate impact on services that entail significant equipment and supply costs in relation to labor costs. In the case of services necessary for the care of patients needing cochlear implants, the clinical labor rate update would reduce the practice expense relative value units (PE-RVUs) associated with reprogramming by up to 5.8% and the PE-RVUs associated electrocochleography by over 10%.

While we recognize that it may be appropriate to update the non-physician clinical labor rates used to determine practice expense payment under the PFS, we believe that considerably more analysis should be performed to determine how the cost of this update should be allocated among PFS services. CMS itself acknowledges that, under the Proposed Rule, the cost of updating clinical labor rates would be born disproportionately by services whose practice expenses are principally comprised of equipment and supply costs. In fact, if the Proposed Rule is adopted without change, Medicare will pay only approximately 44 cents on the dollar for the direct costs (equipment, supply and labor costs) associated with PFS services, including the cochlear implant- related services that are critical to those with substantial hearing loss.

I. Cochlear Implantation, Programming and Related Services

Surgery for a cochlear implant, which often entails intraoperative electrocochleography, is only the beginning of a process of gaining hearing acuity. Accurate programming and periodic reprogramming are critical to patient outcomes both in the peri-operative period and over the long term. The initial cochlear implant programming is provided two to four weeks following surgery and follow-up reprogramming procedures are critical to the proper functioning of the device and to the effective restoration of hearing capabilities. These services are distinct, primary services that are independent of the surgery and performed by personnel with specialized education and training. Services provided to patients include auditory electrophysiology measurements and the collection of behavioral data in order to reprogram and enhance the way the device stimulates the auditory nerve. Overall, the clinical process for cochlear implant services is similar to other non-invasive electrophysiological diagnostic and treatment services typically provided by audiologists. Proper programming is often time-intensive but critical for all patients including older adults who may have been severely to profoundly deaf for many years prior to receiving the cochlear implant.

The need for accessible and convenient programming and re-programming services cannot be overemphasized, and this need is currently satisfied primarily in office-based settings whose Medicare payments are determined under the PFS. In fact, 2018 Medicare utilization data indicates that less than 4% of the Medicare utilization of CPT codes typically used for cochlear programming and related services are performed in facility settings.

One of the major concerns of the ACI Alliance is access to appropriate surgical and post-surgical care for patients who could benefit from hearing restoration via cochlear implants. When reimbursement for services does not reflect the complexity of the service or the actual costs involved, providers underinvest in clinical care and patients experience long wait times and/or low-quality care. This is currently the case with cochlear implants in many areas of the country: It is not unusual for patients in these areas to experience three-month wait times. The proposed reductions would only exacerbate this existing barrier to access.

II. Cochlear Implant-Related Services Practice Expenses

Cochlear implant reprogramming typically requires extensive equipment including:

- Computer, desktop, w-monitor
- Video SVHS VCR (medical grade)
- Audiometer, clinical-diagnostic
- Audiometric soundproof booth (exam and control rooms)
- Cochlear implant programming system
- Cochlear implant testing system
- Immittance, middle-ear analyzer

According to CMS data, the total cost for this equipment is in the range of \$71,902. Likewise, the equipment costs associated with electrocochleography costs \$ 57,552, according to the CMS direct cost database.

The clinical labor involved in the performance of these procedures is generally performed by a physician or audiologist and accounted for through physician work RVUs (W- RVUs) under the PFS and not through PE-RVUs. Because equipment direct costs are relatively high and because none of the labor costs involved in the provision of these procedures are counted as practice expenses, these services are adversely and disproportionately impacted by an update of direct labor rates described in the Proposed Rule.

III. Spreading the Costs involved in Updating Clinical Labor Rates

While we understand CMS’ concerns that the clinical labor rates used to establish PFS practice expense allowances have not been updated since 2006, we do not believe that the cost of this labor rate update should be borne disproportionately by equipment and supply-heavy services, as CMS proposes. In fact, equipment-heavy services are those least able to accommodate sharp and sudden payment reductions, since equipment costs—including the types of equipment necessary to perform reprogramming-- are fixed.

This disproportionate impact occurs because, under the PE formula, the aggregate amount dedicated to payment for direct costs (which includes labor, equipment, and supplies) (hereafter the direct cost “pool”) is capped. In order to ensure that direct costs do not exceed their designated percentage of total practice expenses, CMS applies a “direct scaling adjustment (Dir.Adj) which essentially reduces all direct costs proportionately so that aggregate direct costs “fit” into the direct cost pool. So when aggregate labor costs increase as the result of the proposed labor rate update, a greater proportion of the direct cost pool is dedicated to labor and a relatively smaller portion is dedicated to equipment and supplies. We understand that it is this “scaling” that results in proposed 2022 allowances that pay only 44 cents on the dollar for the equipment, supplies, and clinical labor involved in the provision of PFS services.

However, the size of the direct cost pool –and therefore the “scaling” factor--are determined based on data collected through the PPIS survey in 2007-2008 and are based on data from 2006: The 2006 PPIS data determine the size of the direct cost pool in relation to the indirect cost pool and therefore determines the size of the direct cost pool. But is this split between direct and indirect costs still correct now, in light of the significant increase in clinical labor costs that have taken

place since 2006 and that CMS now proposes to include in the direct cost pool? It is not appropriate to use updated labor rate data without also updating the relative sizes of the direct and indirect practice expense “pools” and to establish a new “scaling factor” based on the current relationship between direct and indirect costs.

We understand that CMS does, in fact, intend to update the PPIS data, but this process is likely to take a number of years. For this reason, we recommend that CMS delay its labor rate update for a year and work with affected stakeholders to find a way to spread the cost of increasing clinical labor rates more broadly among all PFS services, pending update of the PPIS data.

IV. Site of Service Shifts

We believe that reducing Medicare payment for office-based reprogramming and related services is penny wise and pound foolish. Under the Proposed Rule, Medicare would pay only approximately \$21-\$29 for reprogramming services provided to Medicare patients in office settings than the amount that would be paid if the same procedure were performed in a hospital outpatient setting where the hospital, would bear the cost of the specialized equipment overhead and related expenses involved. This payment is clearly insufficient to cover the costs involved and strongly incentivizes a shift from office to hospital outpatient settings, thereby increasing Medicare and patient costs and reducing access.

The following chart compares the amounts proposed to be paid in office vs. hospital outpatient settings in 2022 for various cochlear implant, programming and related services:

CPT ¹ /	Description	HOPPS Pay 2022 (P)	PFS Pay 2022 (P)
92601	Cochlear implt f/up exam <7	\$ 143.21	\$ 75.90
92602	Reprogram cochlear implt <7	\$ 143.21	\$ 52.39
92603	Cochlear implt f/up exam 7/>	\$ 143.21	\$ 68.18
92604	Reprogram cochlear implt 7/>	\$ 143.21	\$ 44.00
92626	Eval aud funcj 1st hour	\$ 143.21	\$ 36.61
92627	Eval aud funcj ea addl 15	n/a	\$ 8.73
92570	Acoustic immitance testing	\$ 143.21	\$ 12.43
92584	Electrocochleography	\$ 143.21	\$ 69.52

Medicare payment reductions of the magnitude proposed are likely to incentivize the shift of these services to hospital settings, which are more costly both for the Medicare program and for patients. In addition, the inadequacy of the Medicare payment rates for office-based reprogramming and related services has the potential to make these services even less easily accessible and to disincentivize patients from scheduling medically necessary maintenance of their devices. Finally, we strongly urge CMS to consider so substantially reducing Medicare payment for office-based services at a time when hospital resources are stretched and hospital settings problematic as the result of the ongoing pandemic.

For these reasons, the ACI Alliance respectfully requests CMS to delay updating the clinical labor rates for a year and to further consider how the cost of such an update could be more equitably shared among PFS services in a manner that preserves access to cochlear implant related services in office settings.

Respectfully,

A handwritten signature in black ink, appearing to read "Donna L. Sorkin". The signature is fluid and cursive, with a long horizontal stroke at the end.

Donna L. Sorkin MA Executive Director
American Cochlear Implant Alliance
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