



March 23, 2020

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Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Coordinating Care from Out-of-State Providers for Medicaid Eligible Children with Medically Complex Conditions; Request for Information (CMS-2324-NC).

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Request for Information regarding the coordination of care from out-of-state providers for Medicaid-eligible children with medically complex conditions.¹ ARM shares the agency's desire to identify best practices for using out-of-state providers to provide care to children with medically complex conditions and to determine how care is coordinated for such children when that care is provided by out-of-state providers.

ARM is an international multi-stakeholder advocacy organization that promotes legislative, regulatory, and reimbursement initiatives necessary to facilitate access to life-giving advances in regenerative medicine worldwide. ARM comprises more than 350 leading life sciences companies, research institutions, investors, and patient groups that represent the regenerative medicine and advanced therapies community. ARM takes the lead on the sector's most pressing and significant issues, fostering research, development, investment, and commercialization of transformational treatments and cures for patients worldwide. The regenerative medicine and advanced therapies sector is the next frontier in the fight against some of society's most devastating diseases and disorders.

As of year-end 2019, ARM estimates there are 987 regenerative medicine and advanced therapies developers worldwide sponsoring 1,066 clinical trials across dozens of indications, including oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.² Many of these diseases do not discriminate based on age and unfortunately also afflict children. As such, ARM's members have current, unique, and particular experiences helping families coordinate care that treats life threatening diseases across state lines.

¹ 85 Fed. Reg. 3330 (Jan. 21, 2020).

² [Alliance for Regenerative Medicine. 2019 Annual Report. Released March 5, 2020. https://alliancerm.org/sector-data/2019-annual-report](https://alliancerm.org/sector-data/2019-annual-report)

Based on these experiences, ARM's comments focus on improving travel support, assuring adequate and timely reimbursement, and expedited provider access in order to reduce barriers that prevent children from receiving care from out-of-state providers in a timely fashion. ARM further suggests improvements toward creating processes for screening and enrolling out-of-state providers in Medicaid, and how to streamline such processes for out-of-state providers to reduce the burden of such processes on them. It is worth noting that while this RFI focuses on children with medically complex conditions, many adults face similar challenges when seeking appropriate care.

I. Executive Summary:

- Consistent with recent Office of Inspector General (OIG) Guidance³, CMS should permit manufacturers to pay for travel and lodging expenses for the patient of a Medicaid Health Home and their immediate family.
- CMS should eliminate reimbursement as an access barrier by requiring states to reimburse providers or facilities 100 percent of the applicable Medicare rate for that facility or provider.
- To reduce administrative burden, CMS should create one standardized process for all the states to use to simply verify that the patient meets the medically accepted indication of the physician prescribed gene, regenerative or immune therapies and to approve and credential a facility or provider to administer the therapy to out of state patients.

II. Lack of Travel and Lodging Funds is a Financial Barrier to Access That Prevents Children with Medically Complex Conditions from Receiving Care from Out-of-State Providers in a Timely Fashion

In the case of many gene, regenerative, and immuno therapies the nearest treating facility may be out-of-state considering the highly needed specialization of providers that would need to administer these innovative therapies. In addition, there may only be a few specialized physicians treating a rare disease spread throughout the country, requiring most patients (and especially those living in rural areas) to travel for care. These factors lead patients to seek expert opinions and treatment out-of-state without the certainty of meaningful access and appropriate reimbursement for providers and facilities that provide the care.

Gene, regenerative, and immuno therapies often have complicated administering procedures that require special personnel and facility departments to ensure safe administration. In addition, the gene, regenerative, or immuno therapy

³ See recent OIG advisory opinion: <https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-02.pdf>

may require the monitoring of patients post administration that may last anywhere from hours to days to weeks. As such, only certain providers may be qualified or eligible to administer the gene, regenerative, or immuno therapy. Many of ARM's members work closely with facilities to ensure that the facility can safely administer the gene, regenerative, or immuno therapy and then monitor the patient, either in the facility or nearby. This effort typically leads to a facility being designated by the manufacturer as a facility eligible to administer the gene, regenerative, or immuno therapy. This series of facts and requirements often leads to a small subset of facilities that can safely administer the gene, regenerative, or immuno therapy.

This narrow network of facilities often requires patients to travel in order to access a gene, regenerative, or immuno therapy. ARM appreciates that CMS recognizes that this financial burden, especially in the Medicaid population, and creates a significant burden toward access.⁴ Traveling to an out-of-state institution adds additional strain to the patient and family. Lodging, gas/airfare, food, childcare for children remaining at home, and other incidentals add a tremendous burden to patients. State Medicaid coverage and payment for travel assistance to out-of-state providers (including lodging, travel, and meals) varies and is often limited to a very basic non-emergency medical transportation (NEMT) benefit. Financial support to cover these services would be welcomed for the safety net population.

ARM therefore urges CMS to issue formal guidance when the nearest site is greater than 100 miles or two hours from the patient's primary residence. In particular, CMS should identify a minimum coverage standard for these expenses and encourage states to develop comprehensive, transparent policies that describe what costs are covered, under what circumstances, and any limitations in place.

Some manufacturers have, in the past and perhaps currently, coordinated and/or supported travel costs for commercial-pay patients. However, the inconsistency in type and level of support can cause greater confusion and inconsistent care for the patient.

The recent OIG opinion⁵ regarding triggering of the Anti-Kickback statute by travel/lodging payments suggests the OIG will not pursue sanctions when the manufacturer carries out travel support that meets pre-specified guidelines. Further codification of this language may provide manufacturers necessary legal clarity in offering these benefits to Medicaid/CHIP beneficiaries that are participating in a Medicaid/CHIP Health Home.

III. To increase Access, CMS Should Reimburse the Provider/Facility 100 Percent of Applicable Medicare Rate for that Facility or Provider for the Gene, Regenerative, or Immuno Therapy

⁴ 85 Fed. Reg. at 3333.

⁵ OIG Advisory Opinion No 20-02, 21 January 2020.

Once the patient needs to be treated out-of-state, ARM believes that the reimbursement for the gene, regenerative, or immuno therapy should not be a barrier. In many cases, the Medicaid beneficiary's home state may have a different reimbursement methodology for reimbursing providers than the state the provider is located in. This could lead to lower reimbursement rates for the out-of-state hospital/provider as federal law requires that the out-of-state institution be reimbursed at the same level as if the patient was being treated within their home state. In addition, given the complicated process, facilities and providers know that reimbursement is often delayed, which in turn, may effectively deny care for such a patient. Related, if a treatment is available, the out-of-state provider may want to oversee initial treatment with the therapy to ensure patient tolerability, monitor safety and overall ensure patient's needs are being met, before releasing the patient for continued monitoring and/or treatment in the their home state. However, if the patient's home state has a challenging reimbursement environment, then the provider may not be able to financially bear the costs of treatment.

Further delays result from the significant challenge associated with the contracting process between the states, to the point that many states/sites significantly limit from which states they accept patients. ARM believes that reliable assurances of a predictable and appropriate reimbursement rate would create more confidence in contracting between states.

The statute clearly states the reimbursement methodology and amount for the additional services provided to coordinate care for a Medicaid patient in a Health Home.⁶ The statute, however, is silent on the reimbursement methodology or rate for the item being provided to the Health Home patient out-of-state. As stated above, this rate and the time of the reimbursement is a significant barrier toward access. As such, ARM recommends that CMS adopt policies that ensure adequate reimbursement for all therapies and timely provider reimbursement across all state Medicaid programs so that access to care is equitable across the states. Specifically, ARM urges CMS to reimburse the gene, regenerative, or immuno therapy at 100 percent of the applicable Medicare rate for that facility or provider. By eliminating reimbursement uncertainty CMS can assure appropriate access to a lifesaving gene, regenerative, or immuno therapy for very vulnerable, young, and sick patients.

IV. CMS Should Create One Standardized Process for All the States to Use to Satisfy Medical Necessity and Approve a Facility or Provider to Administer a Gene, Regenerative, or Immuno Therapy.

As CMS notes in the RFI, there are many challenges with enrolling and/or screening out-of-state providers. Additionally, there are often referral or consult requirements that vary by state that must occur before a gene, regenerative, or immuno therapy can be administered. Unfortunately, these processes vary by state

⁶ Social Security Act (SSA) §1945A(c)(1).

and can therefore dramatically increase the time to access. The time it takes to credential a provider or facility, added to the time it takes to navigate the prior authorization process is time better spent receiving care.

- a. Referral and consult requirements as a barrier to timely access to care for children traveling out-of-state

Many states use a prior authorization process to verify that the prescribed treatment meets the drug's FDA approved medically accepted indication⁷. Notably, while state Medicaid programs and their contracted managed care organizations (MCOs) may impose prior authorization requirements on treatments and drugs, the Medicaid drug rebate statute⁸ does not allow for prior authorization (or other utilization management techniques) to be used as a vehicle to deny coverage for a drug's medically accepted indication. Prior authorization is a time-limited, administrative process to ensure the treating physician has prescribed the Medicaid covered outpatient drug for a medically accepted indication.

In particular, it has taken approximately 200 days longer for out-of-state Medicaid patients to receive a gene therapy product than their commercially insured counterparts. As such, ARM believes that this prior authorization process shall be adjudicated within 48 hours for urgent requests and 96 hours for all other requests.

- b. Provider screening and enrollment challenges as a barrier to timely access to care for children traveling out-of-state

For a provider/facility to be assured of reimbursement for treating a patient from an out-of-state Medicaid Program, the institution is required to credential itself with that Medicaid Program. Furthermore, the provider is not the only entity the needs to undergo the credentialing process. Before a clinician can provide Medicaid-related care, federal law requires that she or he must undergo a background screening before enrolling in a state's Medicaid program. State Medicaid agencies are responsible for carrying out both screening and enrollment. Although the goal—detecting and weeding out providers who might pose fraud or abuse risks—is a good one, the process can impede a child's access to care because states regularly require providers already enrolled and in good standing in their home state, or through Medicare, to go through subsequent screens in order to treat patients from another state.

- c. CMS should implement a nationwide singular provider screening, consulting and enrollment process

The clinical conditions of the patients eligible for Health Home services often require immediate access to care. ARM believes that CMS can streamline these processes by developing a singular process and requirements for providers or

⁷ A "medically accepted indication" means "any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act" plus off-label uses supported by specified compendia. SSA § 1927(k)(6).

⁸ Social Security Act (SSA) § 1927(k)(6)(42 U.S.C. § 1396r-8(k)(6)).

facilities to meet in order to administer a gene, regenerative, or immuno therapy. Many commercial payers have a single negotiated payment rate process to pay out-of-network providers/facilities when access to that provider/facility is medically necessary. ARM strongly encourages CMS to develop a simple and streamlined process that all the states can utilize to enroll out-of-network providers and satisfy clinical concerns. By creating one process, CMS will greatly reduce administrative burdens and increase access to medically necessary therapies for Medicaid/CHIP patients in a Health Home. In particular, ARM recommends that CMS look to the Medicaid Provider Enrollment Compendium (MPEC) guidelines as the start of a minimum federal standard. We would be happy to work with the Agency to identify how to adapt those guidelines to serve such a role and note that the majority of the criteria the MEPC guidelines lay out could form such a minimum standard without alteration.

Additionally, hospitals are not keen to admit or volunteer information relating to the State Medicaid Programs they are currently credentialed with, to avoid becoming a funnel for multiple out-of-state Medicaid patients from across the country. These hospitals cannot afford to take on the sole burden of treating all of these patients. Trying to determine which centers are credentialed in various states presents a significant challenge that a patient/referring physician would face. If hospitals could provide more transparency regarding which states they hold approved credentialing, it would certainly help to streamline the process for patients and providers from out-of-state as well.

V. Conclusion

In conclusion, ARM believes that the field of regenerative medicine has the potential to heal people and bend the health cost curve toward lower long-term costs and higher quality outcomes. This trend is already evident by several approved and marketed first-generation regenerative medicine products that are demonstrating both clinical and cost reduction value. Specifically, by reducing hospital care, the need for physician, clinical and professional services, nursing, and home healthcare, we could substantially reduce overall healthcare expenses. ARM is confident that meaningful improvements in clinical outcomes and cost reduction can be accomplished through regenerative medicine technologies.

ARM thanks the agency for its many proposals and statements in the RFI and looks forward to working with CMS to establish policies that promote timely access to physician-prescribed gene, regenerative, and immuno therapies in both the near term and long. Please free to contact me at 202-320-7602 with questions.

Sincerely,



Robert J. Falb
Director, U.S. Policy and Advocacy