



STATE OF VERMONT
JOINT FISCAL OFFICE

MEMORANDUM

To: Joint Fiscal Committee members
From: Sorsha Anderson, Senior Staff Associate
Date: October 23, 2025
Subject: Grant Request - JFO #3267

Enclosed please find one (1) item, which the Joint Fiscal Office has received from the Administration.

JFO #3267: \$74,826.00 to the Agency of Human Services, Department of Vermont Health Access from the Center for Medicare and Medicaid Innovation. Funds are to test a potential partnership among CMS, Manufacturers and DVHA to better serve Vermonter's access to gene therapies for rare and severe diseases, particularly in underserved communities. *[Received October 20, 2025]*

Please review the enclosed materials and notify the Joint Fiscal Office (Sorsha Anderson: sanderson@leg.state.vt.us) if you have questions or would like this item held for legislative review. Please submit concerns by **November 10, 2025**, or we will assume that you agree to consider as final the Governor's acceptance of this request.

**State of Vermont**

Department of Finance & Management
109 State Street, Pavilion Building
Montpelier, VT 05620-0401

Agency of Administration

[phone] 802-828-2376

STATE OF VERMONT FINANCE & MANAGEMENT GRANT REVIEW FORM

Grant Summary:		This grant includes funding for DVHA personnel participating, with CMS and manufacturers, in the Cell and Gene Therapy Access Model.			
Date:		9/8/2025			
Department:		Department of Vermont Health Access			
Legal Title of Grant:		Cell and Gene Therapy (CGT) Access Model			
Federal Catalog #:		93.885			
Grant/Donor Name and Address:		CMS, Center for Medicare and Medicaid Innovation (CMMI)			
Grant Period:	From:	8/1/2025	To:	12/31/2035	
Grant/Donation		74,826			
	SFY 1	SFY 2	SFY 3	Total	Comments
Grant Amount:	\$48,416	\$26,409	\$	\$74,826	
Position Information:		# Positions	Explanation/Comments		
		0			
Additional Comments:		This specific grant award has an budget end date of 12/31/26 and the period of performance has an end date of 12/31/2035 (which is what is included in the AA-1).			
Department of Finance & Management		Adam Greshin Digitally signed by Adam Greshin Date: 2025.09.11 10:48:37		(Initial)	
Secretary of Administration		Nick Kramer E710487A28FB404...		(Initial)	
Sent To Joint Fiscal Office		Anna Reinold		Date	
		REVIEWED By Anna Reinold at 8:19 pm, Oct 20, 2025			





State of Vermont
Agency of Human Services
Department of Vermont Health Access
NOB 1 South, 280 State Drive
Waterbury, VT 05671-1010
dvha.vermont.gov

TO: Sarah Clark (or Designee), Secretary, Agency of Administration
Joint Fiscal Office

FROM: Jenney Samuelson, Secretary, Agency of Human Services
DaShawn Groves, Commissioner, Department of Vermont Health Access

Initial
DG

8/20/2025

DATE: August 14, 2025

SUBJECT: Request for Grant Acceptance AA-1 Expedited Review Request
Cell and Gene Therapy (CGT) Access Model

In Spring 2025, the Department of Vermont Health Access (DVHA) applied for funding under CMS' Centers for Medicare and Medicaid Innovation (CMMI) in support of a partnership among CMS, Manufacturers, and States related to gene therapies could offer better and more equitable access to treatment for beneficiaries with rare and severe diseases, including those in underserved communities, and how that access may translate into improved quality and health outcomes. This model was developed and managed by CMMI and named the Cell and Gene Therapy (CGT) Access Model.

The initial Notice of Award is for the period of August 1, 2025, through December 31, 2026 for Budget Period 1 in the amount of \$74,826. The first budget period is for seventeen months before moving to a twelve-month period for Budget Periods 2-10. This grant award may be extended through December 31, 2035.

DVHA is requesting expedited review and approval of the attached Request for Grant Acceptance Form AA-1 for the CGT Access Model award.

cc:

Tracy O'Connell, AHS
Stephanie Barrett, DVHA
Tim Metayer, AoA

DocuSigned by:
Tracy O'Connell
E3063208A5F482
8/26/2025

STATE OF VERMONT REQUEST FOR GRANT (*) ACCEPTANCE (Form AA-1)

BASIC GRANT INFORMATION				
1. Agency:		Agency of Human Services		
2. Department:		Department of Vermont Health Access		
3. Program:		Medicaid Pharmacy		
4. Legal Title of Grant:		Cell and Gene Therapy (CGT) Access Model		
5. Federal Catalog #:		93.885		
6. Grant/Donor Name and Address: CMS, Center for Medicare and Medicaid Innovation (CMMI)				
7. Grant Period:	From:	8/1/2025	To:	12/31/2035
8. Purpose of Grant: The Center for Medicare and Medicaid Innovation (CMMI) has announced that they will test whether a partnership among CMS, Manufacturers, and States related to gene therapies could offer better and more equitable access to treatment for beneficiaries with rare and severe diseases, including those in underserved communities, and how that access may translate into improved quality and health outcomes. This model was developed and managed by CMMI and appropriately named the Cell and Gene Therapy (CGT) Access Model.				
9. Impact on existing program if grant is not Accepted: The extraordinary costs of new gene therapies for sickle cell disease may present a barrier to access among those insured by state Medicaid programs. Vermont's Medicaid Program has not yet executed outcomes based agreement contracts for gene therapies due to the complexity in negotiating endpoints and thresholds with manufacturers, the State's lack of leverage stemming from the lack of alternative treatments and statutory coverage obligations as well as the small population size, and finally the burden of data collection and continuous level of effort for evaluation over multiple years. The Vermont Medicaid Program has chosen to fully participate in the CGT Access Model, to not only facilitate access and treatment options to its covered population, but to reduce the net costs of these high-cost gene therapies. The model will likely enhance savings, improve stability, and result in greater financial predictability, rebates, and longterm reductions in health expenditures.				
10. BUDGET INFORMATION				
	SFY 1	SFY 2	SFY 3	Comments
Expenditures:	FY 2026	FY 2027	FY	
Personal Services	\$	\$	\$	
Operating Expenses	\$48,416	\$26,409	\$	
Grants	\$	\$	\$	
Total	\$48,416	\$26,409	\$	
Revenues:				
State Funds:	\$	\$	\$	
Cash	\$	\$	\$	
In-Kind	\$	\$	\$	
Federal Funds:	\$	\$	\$	
(Direct Costs)	\$	\$	\$	
(Statewide Indirect)	\$	\$	\$	
(Departmental Indirect)	\$	\$	\$	

STATE OF VERMONT REQUEST FOR GRANT (*) ACCEPTANCE (Form AA-1)

Other Funds:	\$	\$	\$	
Grant (source CMS/DMMI)	\$48,416	\$26,409	\$	
Total	\$48,416	\$26,409	\$	

Appropriation No:	3410010000	Amount:	\$74,826
			\$
			\$
			\$
			\$
			\$
			\$
		Total	\$74,826

PERSONAL SERVICE INFORMATION

11. Will monies from this grant be used to fund one or more Personal Service Contracts? ☐ Yes ☒ No
 If "Yes", appointing authority must initial here to indicate intent to follow current competitive bidding process/policy.

Appointing Authority Name: _____ Agreed by: _____ (initial)

12. Limited Service Position Information:	# Positions	Title
Total Positions		

12a. Equipment and space for these positions:

☐ Is presently available. ☐ Can be obtained with available funds.

13. AUTHORIZATION AGENCY/DEPARTMENT

I/we certify that no funds beyond basic application preparation and filing costs have been expended or committed in anticipation of Joint Fiscal Committee approval of this grant, unless previous notification was made on Form AA-1PN (if applicable):

Signed by: DaShawn Groves
 Title: Commissioner
 AAF9E7992536479

Date: 8/26/2025

Signed by: Kristin McLure
 Title: Deputy Secretary
 2D24B62BE34A4C5

Date: 8/28/2025

14. SECRETARY OF ADMINISTRATION

☒ NK
☐

Approved:

Signed by: Nick Kramer
 (Secretary or designee signature)
 E710487A28FB404

Date: 9/16/2025 | 10:18:26

15. ACTION BY GOVERNOR

☒ Check One Box:
☒ Accepted

(Governor's signature)

☐ Rejected

Date: 10/15/25

16. DOCUMENTATION REQUIRED

STATE OF VERMONT REQUEST FOR GRANT (*) ACCEPTANCE (Form AA-1)

Required GRANT Documentation	
☒ Request Memo ☐ Dept. project approval (if applicable) ☒ Notice of Award ☐ Grant Agreement ☒ Grant Budget	☐ Notice of Donation (if any) ☐ Grant (Project) Timeline (if applicable) ☐ Request for Extension (if applicable) ☐ Form AA-1PN attached (if applicable)
End Form AA-1	
(*) The term “grant” refers to any grant, gift, loan, or any sum of money or thing of value to be accepted by any agency, department, commission, board, or other part of state government (see 32 V.S.A. §5).	



Department of Health and Human Services
Centers for Medicare & Medicaid Services

Notice of Award

Award# 2P2CMS332032-01-00

FAIN# 2P2CMS332032

Federal Award Date: 08/01/2025

Recipient Information

1. Recipient Name

HUMAN SERVICES VERMONT AGENCY OF
280 State Dr
Waterbury, VT 05671-9501
[NO DATA]

2. Congressional District of Recipient
00

3. Payment System Identifier (ID)
1036000264D4

4. Employer Identification Number (EIN)
036000264

5. Data Universal Numbering System (DUNS)
809376155

6. Recipient's Unique Entity Identifier (UEI)
YLQARK22FMQ1

7. Project Director or Principal Investigator

Ms. Lisa Brouillette Hurteau
Pharmacy Director
Lisa.Hurteau@vermont.gov
802-585-8629

8. Authorized Official

Mrs. Meaghan Kelley
Financial Director I
Meaghan.Kelley@Vermont.gov
802-585-0302

Federal Agency Information

Office of Acquisitions and Grants Management

9. Awarding Agency Contact Information

Makaria J Martin
Grants Management Specialist
makaria.martin2@cms.hhs.gov
667-414-0859

10. Program Official Contact Information

Steve Chu
Project Officer
steve.chu@cms.hhs.gov
410-786-1489

Federal Award Information

11. Award Number

2P2CMS332032-01-00

12. Unique Federal Award Identification Number (FAIN)

2P2CMS332032

13. Statutory Authority

Section 1115A of the Social Security Act

14. Federal Award Project Title

Vermont Cell and Gene Therapy Grant Project

15. Assistance Listing Number

93.885

16. Assistance Listing Program Title

Cell and Gene Therapy (CGT) Access Model

17. Award Action Type

New

18. Is the Award R&D?

No

Summary Federal Award Financial Information

19. Budget Period Start Date 08/01/2025 - **End Date** 12/31/2026

20. Total Amount of Federal Funds Obligated by this Action \$74,826.00

20a. Direct Cost Amount \$74,826.00

20b. Indirect Cost Amount \$0.00

21. Authorized Carryover \$0.00

22. Offset \$0.00

23. Total Amount of Federal Funds Obligated this budget period \$0.00

24. Total Approved Cost Sharing or Matching, where applicable \$0.00

25. Total Federal and Non-Federal Approved this Budget Period \$74,826.00

26. Period of Performance Start Date 08/01/2025 - **End Date** 12/31/2035

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Period of Performance \$74,826.00

28. Authorized Treatment of Program Income

ADDITIONAL COSTS

29. Grants Management Officer - Signature

Mr. Gabriel Nah
Grants Management Officer

30. Remarks

Funds have been authorized in accordance with the final negotiated budget dated July 31, 2025.

Please see the attached Recipient Specific, Program, and Standard Terms and Conditions.



Department of Health and Human Services
Centers for Medicare & Medicaid Services

Notice of Award

Award# 2P2CMS332032-01-00

FAIN# 2P2CMS332032

Federal Award Date: 08/01/2025

Recipient Information

Recipient Name

HUMAN SERVICES VERMONT AGENCY OF
280 State Dr
Waterbury, VT 05671-9501
[NO DATA]

Congressional District of Recipient

00

Payment Account Number and Type

1036000264D4

Employer Identification Number (EIN) Data

036000264

Universal Numbering System (DUNS)

809376155

Recipient's Unique Entity Identifier (UEI)

YLQARK22FMQ1

31. Assistance Type

Cooperative Agreement

32. Type of Award

Other

33. Approved Budget

(Excludes Direct Assistance)

I. Financial Assistance from the Federal Awarding Agency Only

II. Total project costs including grant funds and all other financial participation

a. Salaries and Wages	\$48,607.00
b. Fringe Benefits	\$26,219.00
c. Total Personnel Costs	\$74,826.00
d. Equipment	\$0.00
e. Supplies	\$0.00
f. Travel	\$0.00
g. Construction	\$0.00
h. Other	\$0.00
i. Contractual	\$0.00
j. TOTAL DIRECT COSTS	\$74,826.00
k. INDIRECT COSTS	\$0.00
l. TOTAL APPROVED BUDGET	\$74,826.00
m. Federal Share	\$74,826.00
n. Non-Federal Share	\$0.00

34. Accounting Classification Codes

FY-ACCOUNT NO.	DOCUMENT NO.	ADMINISTRATIVE CODE	OBJECT CLASS	ASSISTANCE LISTING	AMT ACTION FINANCIAL ASSISTANCE	APPROPRIATION
5-5991982	2P2332032A	2P2	4158	93.885	\$74,826.00	75-X-0522

AWARD ATTACHMENTS

HUMAN SERVICES VERMONT AGENCY OF

2P2CMS332032-01-00

-
1. Recipient-Specific Terms and Conditions
 2. CGT Program Terms and Conditions BP1
 3. Standard Terms and Conditions August 2025

**Center for Medicare & Medicaid Innovation
Cell and Gene Therapy (CGT) Access Model
Recipient Specific Terms and Conditions**

Recipient: Vermont Agency of Human Services

- 1. General.** In addition to all Standard Terms and Conditions and Program Terms and Conditions, Recipient is subject to the following Recipient Specific Terms and Conditions. The Centers for Medicare & Medicaid Services (CMS) may add or otherwise amend these Recipient Specific Terms and Conditions as necessary at any point during the CGT Access Model Period of Performance.
- 2. Administrative.** In Section K. Audit of the Business Assessment of Applicant Organization, the Recipient noted that their organization has 3 corrective actions for audit findings. One of the audit findings (Number 2023-030) has an in-progress CAP under 2022-038. The Recipient explained that this audit finding is “In Process. Scheduled completion Date March 31, 2025: Annual review of FFATA rules and regulations including subawards review. Anticipated to be marked as complete next audit period.” **Please let CMS know when this audit finding (Number 2023-030) has been marked complete.**

If you have any questions, please contact your Grants Management Specialist for assistance.

Centers for Medicare & Medicaid Services (CMS)
Cell and Gene Therapy (CGT) Access Model
Budget Period 1: August 1, 2025 - December 31, 2026
Program Terms and Conditions

The requirements contained in the Notice of Funding Opportunity (NOFO), FON# CMS-2P2-25-001, are incorporated by reference as Program Terms and Conditions attached to this Notice of Award (NoA), as well as the below additional Program Terms and Conditions for the “Cell and Gene Therapy (CGT) Access Model” Award Program. In the event of any inconsistency between the provisions of these Program Terms and Conditions and the provisions of the NOFO, the provisions of these Program Terms and Conditions will prevail.

The Recipient must comply with the representations, assurances and certifications made by the Recipient in the Recipient’s application, including any revisions or amendments approved in writing by CMS.

Definitions

The following definitions apply for purposes of this Program Terms and Conditions document:

- **“Administration Period”** is the time period referred to as “OBA Term” in the NOFO and means the time period during which a VBP SRA between the State and the Manufacturer applies to Model Drugs administered to Model Beneficiaries. For each Model Drug, the Administration Period is specified in the Key Terms.
- **“Application”** means the application submitted by the Applicant in response to the CGT Access Model NOFO, including any attachments, revisions or amendments thereto, which are hereby approved in writing by CMS.
- **“Beneficiary”** means an individual who is enrolled in Medicaid, including individuals enrolled in Title XXI-funded Medicaid expansion CHIP.
- **“Budget Period” or “BP”** means the 17-month period beginning on August 1, 2025, and ending December 31, 2026, for Budget Period 1, and each 12-month period beginning on January 1 and ending on December 31, for Budget Periods 2-10, as described in Section 8, *Cooperative Agreement Period of Performance and Budget Periods*.
- **“Candidate Beneficiary”** means a Beneficiary who meets all of the following criteria:
 - Has a documented medical diagnosis of SCD; and
 - Has the State Medicaid program as the Beneficiary’s primary payer for a State-Selected Model Drug.
- **“Cooperative Agreement” or “Cooperative Agreement Award”** means a legal instrument of financial assistance between CMS and the Recipient consistent with 31 U.S.C. §§ 6302-6305 that:

- Is used to enter into a relationship the principal purpose of which is to transfer anything of value from CMS to the Recipient to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. § 6101(3)); and not to acquire property or services for the federal government or for the federal government's direct benefit or use, and
- Is distinguished from a grant in that it provides for substantial involvement between CMS and the Recipient in carrying out the approved activities under this award (see 31 U.S.C. § 6305(2))
- **“Cooperative Agreement Period of Performance”** means the period beginning on August 1, 2025, and ending on December 31, 2035, for a total of ten years and five months.
- **“Key Terms”** means the central parameters of the agreement negotiated between CMS and a Manufacturer, including but not limited to rebate calculation and amounts, the duration of the agreement, data sharing arrangements, and any options or variations, that will form the basis for an individual VBP SRA between the Manufacturer and the State. The Key Terms for each Model Drug are documented in a document shared with the State through the Medicaid Drug Program portal, as may be revised pursuant to the Recipient's State Agreement with CMS.
- **“Manufacturer”** means a pharmaceutical manufacturer, as described in 42 C.F.R. § 447.502, that meets all of the following criteria:
 - Participates in the MDRP;
 - Holds the New Drug Application(s) or Biologics License Application(s) of a gene therapy with a U.S. Food & Drug Administration (FDA)-approved indication for the treatment of SCD; and
 - Has executed a Participation Agreement under the Model to participate.
- **“MDRP”** means the Medicaid Drug Rebate Program as described in 42 U.S.C. § 1396r-8 and 42 C.F.R. § 447.509.
- **“Measurement Period”** means the time period following administration of the Model Drug during which outcome measures for an individual or cohort will be monitored. For each Model Drug, the Measurement Period is specified in the Key Terms.
- **“Model Beneficiary”** means a Candidate Beneficiary who meets all of the following criteria:
 - Has received an infusion of a State-Selected Model Drug;
 - Has the State Medicaid program as the Beneficiary's primary payer for the infused State-Selected Model Drug;
 - On the date the Beneficiary is infused with the State-Selected Model Drug, a VBP SRA between the State and the Manufacturer of the infused State-Selected Model Drug is in effect; and
 - If the Beneficiary is enrolled in an MCP or Medicaid FFS on the date the Beneficiary is infused with the State-Selected Model Drug, such population is

included in the terms of the VBP SRA between the Manufacturer of the infused State-Selected Model Drug and the State on such infusion date.

- **“Model Drug”** means a gene therapy with an FDA-approved indication for the treatment of SCD for which CMS and the Manufacturer have negotiated Key Terms.
- **“Model Performance Period Start Date”** means the date by which the State shall begin performance in the Model, as specified in the Recipient’s State Agreement with CMS.
- **“Model Performance Year”** means a period of time during the Model Performance Period, as described in the Recipient’s State Agreement with CMS and Section 8, *Cooperative Agreement Period of Performance and Budget Periods*.
- **“NoA”** means Notice of Award.
- **“Non-Competing Continuation Application” or “NCC Application”** means the non-competitive application that Recipient must submit during each Budget Period to receive an award for additional funding in the subsequent Budget Period.
- **“Non-Competing Continuation Award” or “NCC Award”** means the award for additional funding in a subsequent Budget Period following the submission and approval of an NCC Application.
- **“Quarter”** means one of the four periods (each including three months) in a calendar year, as follows:
 - Quarter 1: January 1-March 31
 - Quarter 2: April 1-June 30
 - Quarter 3: July 1-September 30
 - Quarter 4: October 1-December 31
- **“Recipient” or “State”** means the state entity (e.g., State Medicaid Agency) that submitted the Application for CMS’s consideration and received the NoA from CMS. This does not include Subrecipients.
- **“SCD”** means sickle cell disease, which is an inherited, genetic blood disorder that causes blood cells to become rigid, abnormally shaped, and “sticky” due to the “S” form of hemoglobin (HbS) – the protein that carries oxygen throughout the body – resulting in blood flow obstruction, pain, anemia, and serious complications. This symptom list is not exhaustive.
- **“SRA”** means CMS-authorized supplemental rebate agreement as described in 42 C.F.R. § 447.502.
- **“State Agreement”** means the written agreement between CMS and the Recipient that governs the Recipient’s participation in the CGT Access Model.
- **“State-Selected Model Drug”** means a Model Drug for which the State has chosen to enter into a VBP SRA with the Manufacturer reflecting the Key Terms for the Model Drug.
- **“Subrecipient”** means a non-federal entity that receives a subaward from the Recipient to carry out activities related to the award.

- **“Terms and Conditions of Award”** means, collectively, the following: (1) Recipient Specific Terms and Conditions (RSTCs) (if applicable); (ii) these Program Terms and Conditions; and (iii) the Standard Terms and Conditions incorporated by reference in, and included as an attachment to, the NoA.
- **“VBP”** means value-based purchasing as described in 42 C.F.R. § 447.502.

GENERAL

1. **CMS Center for Medicare and Medicaid Innovation (Innovation Center) Project Officer.** Unless otherwise specified in writing, the name and contact information of the Project Officer assigned responsibility for the technical and programmatic administration aspects of the award is identified in field 10 of the NoA (Program Official Contact Information).
2. **The CMS Grants Management Specialist.** Unless otherwise specified in writing, the Grants Management Specialist assigned responsibility for the financial and administrative aspects (non-programmatic areas) of cooperative agreement administration and questions from Recipient is identified in field 9 of the NoA (Awarding Agency Contact Information).
3. **Notice of Funding Opportunity (NOFO).** All relevant project requirements and definitions outlined in the NOFO (CMS-2P2-25-001) apply to this award and are incorporated into the Terms and Conditions of Award by reference.
4. **State Agreement.** In the event of any conflict between the provisions of the Terms and Conditions of Award and the provisions of the Recipient’s State Agreement with CMS, CMS will work with the Recipient to resolve the conflict to the extent possible.
5. **Statutory Authority.** This award is issued under the authority of Section 1115A of the Social Security Act (the Act) as added by Section 3021 of the Patient Protection and Affordable Care Act (P.L. 111-148). By receiving funds under this award, Recipient is obligated to comply with, and certifies to CMS that it will comply with, the Terms and Conditions of Award.
6. **Role of CMS in a Cooperative Agreement Award.** Under a Cooperative Agreement Award, CMS’ purpose is to support and stimulate the Recipient’s activities by involvement in, and otherwise working jointly with, the Recipient in a partnership role. CMS will not assume direction or primary responsibility for the Recipient’s activities.

The Recipient can expect substantial collaboration, participation, and/or intervention in the oversight of the project by CMS. Substantial involvement may include collaboration or participation by CMS program staff in activities specified in the NoA and, as appropriate, decision-making at specified milestones related to performance (e.g., requiring CMS approval before undertaking the next phase of a project, collaborating in the design of a service delivery model). Substantial involvement pertains to programmatic involvement, not administrative oversight.
7. **Role of the Recipient in a Cooperative Agreement Award.** The Recipient retains ultimate responsibility for coordination and oversight of Model-related activities. The Recipient retains the primary responsibility and dominant role for planning, directing, and executing CGT Access Model activities within the Recipient’s state.
8. **Cooperative Agreement Period of Performance and Budget Periods.** The Cooperative

Agreement Period of Performance for this award is located on the NoA, in field 26 (Summary Federal Award Financial Information). The Cooperative Agreement Period of Performance consists of ten (10) Budget Periods that correspond with eleven (11) Model Performance Years as set forth in Table 1. The NoA details the current budget period in field 19, the funding awarded in field 20, and the approved budget in field 33.

Table 1. *Cooperative Agreement Period of Performance*

Budget Period (BP)	Model Performance Year (PY)	Start Date	End Date	Duration
BP1	PY1 & PY2	August 1, 2025	December 31, 2026	17 months
BP2	PY3	January 1, 2027	December 31, 2027	12 months
BP3	PY4	January 1, 2028	December 31, 2028	12 months
BP4	PY5	January 1, 2029	December 31, 2029	12 months
BP5	PY6	January 1, 2030	December 31, 2030	12 months
BP6	PY7	January 1, 2031	December 31, 2031	12 months
BP7	PY8	January 1, 2032	December 31, 2032	12 months
BP8	PY9	January 1, 2033	December 31, 2033	12 months
BP9	PY10	January 1, 2034	December 31, 2034	12 months
BP10	PY11	January 1, 2035	December 31, 2035	12 months

9. Restriction of Funds. Specific restrictions of funds, if applicable, have been detailed in the Recipient Specific Terms and Conditions of Award (RSTCs). In addition to the restrictions set out in the RSTCs, such restrictions shall include the following:

- a. **Implementation Funding for Budget Period 1.** CMS may restrict a portion of Implementation Funding in Budget Period 1 until the start of CY 2026. Recipient should refer to the Recipient Specific Terms and Conditions to review its Implementation Funding restrictions.
- b. **Milestone Funding.** Milestone Funding will be restricted. Recipient may not draw down Milestone Funding until Recipient demonstrates satisfactory completion of a Milestone Funding project by submitting a full performance report to CMS, and CMS grants approval. See Section 22, *Reporting Linked to Milestone Funding*, for more information about the Milestone Funding Performance Report.
- c. The Recipient must request prior approval for activities or costs to support new Subrecipients, contractual, and consultant agreements not already approved through a NoA. A detailed itemized budget must be provided for all Subrecipients, contractual, and consultant agreements. If this information is unknown at the time of Application or for a subsequent NCC Application, the Recipient must follow-up and provide this information via a Revision (NoA Other) or Revision (Budget) amendment in GrantSolutions as soon as this information can be provided to CMS. Additionally, please see NOFO Appendix I, *Guidance for Preparing a Budget Request and Narrative*, for required contractual and consultant questions the Recipient must address. The Recipient may not incur costs or draw down funds to support these activities until CMS provides approval.

- d. CMS may restrict funding if the Recipient is not compliant with the requirements in the Terms and Conditions of the NoA including performance on the reporting outlined in Section 21, *Reporting Linked to Implementation Funding*, and Section 22, *Reporting Linked to Milestone Funding*. If CMS restricts the Recipient's funding due to non-compliance, CMS may lift this restriction once the Recipient is compliant with the requirements herein.

10. Continued Funding. Continued funding is contingent on satisfactory progress, compliance with the terms and conditions, and the availability of funds. As stated in the Standard Terms and Conditions, Section 24, *Continued Funding*, the Recipient must submit an NCC Application each Budget Period as a prerequisite to continued funding if a Cooperative Agreement Period of Performance is comprised of multiple budget periods. The Recipient must request an NCC Award 90 days before the end of each Budget Period beginning with Budget Period 1, by submitting an NCC Application and any required documents via GrantSolutions.

- a. The CMS Grants Management Specialist will provide instructions for completing and submitting each NCC Application to the Recipient at least 120 days prior to the end of Budget Period 1. If the NCC Application is approved, CMS will issue the Recipient a NCC Award for Budget Period 2 prior to the expiration of Budget Period 1. See the Standard Terms and Conditions, Section 3. *Funding for Recipients* for additional requirements.
- b. The Recipient will not have authority to utilize unobligated funds remaining from Budget Period 1 in Budget Period 2 without prior written approval from CMS. The Recipient may request prior approval from CMS to carry over unobligated funds from Budget Period 1 to Budget Period 2 to complete previously approved activities/costs. The CMS Grants Management Specialist will provide information and instructions on this process.
- c. All of the following are required to achieve satisfactory progress in Budget Period 1 of the CGT Access Model, unless CMS indicates otherwise in writing:
 - i. Submission of all required data, reports, documentation, and deliverables by the Recipient to CMS or its contractor(s) (or its Subrecipient(s) or contractor(s) submits to CMS or its contractor(s) via the Recipient) in support of model activities as detailed in these Program Terms and Conditions.
 - ii. Participation in all technical assistance, monitoring, and evaluation activities and events.
 - iii. Compliance with the Recipient's State Agreement with CMS.
- d. Along with each NCC application, the Recipient must propose any Milestone Funding project to be conducted in the upcoming Budget Period. If CMS approves the project, the Terms and Conditions of Award will stipulate that Milestone Funding associated with the project is to be awarded in the following Budget Period.

11. Use of Funds. The Recipient must only use funds for the purposes stated in the NOFO and the purposes approved by CMS in the Application, including any subsequent budget revisions approved by CMS. The Recipient shall not use award funds to pay for services currently

reimbursable by Medicaid or to supplant existing funding from other sources. CMS prohibits the use of funds under this award for any of the activities/costs outlined in the Standard Terms and Conditions, Section 23, *Prohibited Use of Grant or Cooperative Agreement Funds*, unless an exception is specifically authorized by statute. Additionally, the Recipient cannot use funds for the following activities

- a. Reimbursement of pre-award costs;
- b. Providing individuals with items or services that are already funded through any other source, including, but not limited to, Medicare, Medicaid, and CHIP.

12. Duplication. The Recipient is responsible for ensuring that no federal funds provided under this award are used to provide technical assistance or other services that are duplicative of funds and services authorized under other federal initiatives. The Recipient may be requested by CMS to provide evidence of well-documented internal controls to ensure that resources are used in the most efficient manner and that activities are not duplicative as stated above. If any duplication occurs, the Recipient must notify the CMS Grants Management Specialist and the Project Officer at the time of discovery and provide a mitigation plan to the CMS Grants Management Specialist and to the Project Officer.

REPORTING AND MONITORING REQUIREMENTS

13. Complete and Accurate Submissions. The Recipient must ensure that all data, reports, and documentation that it submits to CMS or its contractor(s) (or that its Subrecipient(s) or contractor(s) submits to CMS or its contractor(s) via the Recipient) in support of model activities are complete and accurate to the best of the Recipient's knowledge, and that such data are submitted in a format that complies with CMS requirements. The Recipient must correct, and facilitate corrections, for any inaccurate or incomplete data, reports, or documentation that it previously submitted to CMS no later than 2 weeks after it or CMS becomes aware of the inaccuracy or incompleteness in a manner and form specified by CMS. The Recipient may be subject to specific remediation actions if CMS does not receive timely, complete, and accurate data, reports, and documentation (see Section 26, *Remediation Actions*, Section 27, *Enforcement Actions*, and Section 28, *Termination by CMS*).

14. Management Tool. CMS reserves the right to require the Recipient to use management tools (Payment Management System, GrantSolutions, or others) for all communications, including without limitation of tracking model data and/or for submitting the programmatic and financial reports. CMS will provide the Recipient with access to these management tools and related instructions.

15. Award Monitoring. CMS will monitor the project to assess Recipient's performance, including identification of potential problems and areas where additional technical assistance might be necessary. CMS monitoring activities may include the following: phone calls, scheduled teleconferences or web conferences between the Recipient and the Project Officer, review of programmatic progress and financial Reports, prior approval requests to utilize funding, spend rates, correspondence between the Recipient and CMS, audit reports, site visits, and other activities and information available to CMS.

During these teleconferences, web conferences, or site visits, the Recipient must be prepared to

substantively discuss the status of activities; any goal revisions; activities with partners and any Subrecipients; any successes/outcomes; any significant challenges/delays the Recipient, Subrecipients, and other individuals and entities involved in the model have encountered and their effect on the project timeline; personnel changes; budgetary changes; technical assistance received and additional assistance needed from CMS; and other project-related issues.

The Recipient must provide CMS-specified data elements for monitoring to CMS and/or its contractor(s) in a form and manner and by a deadline specified by CMS. Data for monitoring include, but are not limited to, notes, agendas and materials discussed during Project Officer phone calls and email communications; programmatic reports; progress toward milestones; and financial expenditure reports.

Nothing in these Program Terms and Conditions shall be construed to limit or otherwise prevent CMS from monitoring the Recipient.

- 16. Communication/Participation.** The Recipient must participate in technical assistance activities as specified in these Program Terms and Conditions. CMS reserves the right to require that the Recipient participates in additional technical assistance activities as needed. The Recipient must disseminate information received from CMS to all internal and external individuals or entities affected by the award to ensure timely and effective communications.

The Recipient must develop and maintain a communications management plan for all internal and external communications with all individuals or entities related to this award such that Recipient maintains timely and effective communications throughout the Cooperative Agreement Period of Performance. The Recipient must provide to the Project Officer an accurate record of contact information for all staff working on this award. At minimum, this contact information must include the staff name, email address, and telephone number.

The Recipient must maintain and update CMS on all changes to staffing contact information throughout the Cooperative Agreement Period of Performance. Further, if CMS establishes a listserv or other means of providing electronic communications, then the Recipient must subscribe to and use that system(s). CMS will notify the Recipient of the applicable listserv(s) to subscribe to or other means of communication, as applicable.

- 17. Progress Reports.** The Recipient must submit required progress reports as further detailed below in Table 2. CMS will provide to the Recipient additional information on the specific requirements and format of the programmatic progress reports.

- a. Quarterly Progress Report.** The Recipient must submit four Quarterly Progress Reports each calendar year to CMS. The Quarterly Progress Report is specific to activities completed and progress achieved during the prior three months.
 - i.** Each Quarterly Progress Report shall include at minimum the status of each element in the state's Model Implementation Plan, a narrative summary of the period's accomplishments, barriers or challenges to meeting element benchmarks, and any additional requirements identified by CMS. Quarterly Progress Reports must also contain the information specified in Section 21, *Reporting Linked to Implementation Funding* and Section 22, *Reporting Linked to Milestone Funding*, as applicable.

- ii. The Quarterly Progress Report is due 30 calendar days after the end of the reporting period.
 - iii. The recipient must complete and electronically submit quarterly progress reports to CMS's grants management data collection platform, GrantSolutions. GrantSolutions can be accessed via the following link: <https://www.grantsolutions.gov>. These reports should be uploaded to GrantSolutions via the Performance Progress Report (PPR) Module.
- b. **Final Progress Report.** The Recipient must submit a final progress report to CMS. This report must provide a cumulative summary of activities completed during the entire Cooperative Agreement Period of Performance, including, but not limited to, a complete discussion of the use of funds for Model activities, analysis of effectiveness or success of the Model, lessons learned, and a description of activities that will be sustained as a result of the Model.
- i. The Final Progress Report is due, along with other required closeout materials, 120 days after the end of the Cooperative Agreement Period of Performance.
 - ii. The recipient must complete and electronically submit a final report to CMS's grants management data collection platform, GrantSolutions. GrantSolutions can be accessed via the following link: <https://www.grantsolutions.gov>. These reports should be uploaded to GrantSolutions via the Performance Progress Report (PPR) Module.
 - iii. All progress reports must be in a format compliant with section 508 of the Rehabilitation Act (29 U.S.C. 794d).¹
 - iv. The absence of satisfactory progress reports may result in CMS deciding to terminate Recipient's Award, and to allocate those funds as determined by CMS. CMS reserves the right to require the Recipient to clarify or provide additional details in these reports.

Table 2. *Due Dates for Submission of Quarterly Progress Reports and Final Progress Report*

Report Type	Reporting Period	Due Date
Quarterly Progress Report 1 (2025 Q3)	August 1 – September 30, 2025	October 30, 2025
Quarterly Progress Report 2 (2025 Q4) *	October 1 – December 31, 2025	January 30, 2026
Quarterly Progress Report 3 (2026 Q1)	January 1 – March 31, 2026	April 30, 2026
Quarterly Progress Report 4 (2026 Q2)	April 1 – June 30, 2026	July 30, 2026
Quarterly Progress Report 5 (2026 Q3) †	July 1 – September 30, 2026	October 30, 2026
Quarterly Progress Report 6 (2026 Q4) *	October 1 – December 31, 2026	January 30, 2027
Quarterly Progress Report 7 (2027 Q1)	January 1 – March 31, 2027	April 30, 2027
Quarterly Progress Report 8 (2027 Q2)	April 1 – June 30, 2027	July 30, 2027
Quarterly Progress Report 9 (2027 Q3) †	July 1 – September 30, 2027	October 30, 2027
Quarterly Progress Report 10 (2027 Q4) *	October 1 – December 31, 2027	January 30, 2028
Quarterly Progress Report 11 (2028 Q1)	January 1 – March 31, 2028	April 30, 2028
Quarterly Progress Report 12 (2028 Q2)	April 1 – June 30, 2028	July 30, 2028

¹ For more information on ensuring 508 compliance: <https://www.hhs.gov/web/section-508/index.html>

Quarterly Progress Report 13 (2028 Q3) †	July 1 – September 30, 2028	October 30, 2028
Quarterly Progress Report 14 (2028 Q4) *	October 1 – December 31, 2028	January 30, 2029
Quarterly Progress Report 15 (2029 Q1)	January 1 – March 31, 2029	April 30, 2029
Quarterly Progress Report 16 (2029 Q2)	April 1 – June 30, 2029	July 30, 2029
Quarterly Progress Report 17 (2029 Q3) †	July 1 – September 30, 2029	October 30, 2029
Quarterly Progress Report 18 (2029 Q4) *	October 1 – December 31, 2029	January 30, 2030
Quarterly Progress Report 19 (2030 Q1)	January 1 – March 31, 2030	April 30, 2030
Quarterly Progress Report 20 (2030 Q2)	April 1 – June 30, 2030	July 30, 2030
Quarterly Progress Report 21 (2030 Q3) †	July 1 – September 30, 2030	October 30, 2030
Quarterly Progress Report 22 (2030 Q4) *	October 1 – December 31, 2030	January 30, 2031
Quarterly Progress Report 23 (2031 Q1)	January 1 – March 31, 2031	April 30, 2031
Quarterly Progress Report 24 (2031 Q2)	April 1 – June 30, 2031	July 30, 2031
Quarterly Progress Report 25 (2031 Q3)	July 1 – September 30, 2031	October 30, 2031
Quarterly Progress Report 26 (2031 Q4) *	October 1 – December 31, 2031	January 30, 2032
Quarterly Progress Report 27 (2032 Q1)	January 1 – March 31, 2032	April 30, 2032
Quarterly Progress Report 28 (2032 Q2)	April 1 – June 30, 2032	July 30, 2032
Quarterly Progress Report 29 (2032 Q3)	July 1 – September 30, 2032	October 30, 2032
Quarterly Progress Report 30 (2032 Q4) *	October 1 – December 31, 2032	January 30, 2033
Quarterly Progress Report 31 (2033 Q1)	January 1 – March 31, 2033	April 30, 2033
Quarterly Progress Report 32 (2033 Q2)	April 1 – June 30, 2033	July 30, 2033
Quarterly Progress Report 33 (2033 Q3)	July 1 – September 30, 2033	October 30, 2033
Quarterly Progress Report 34 (2033 Q4) *	October 1 – December 31, 2033	January 30, 2034
Quarterly Progress Report 35 (2034 Q1)	January 1 – March 31, 2034	April 30, 2034
Quarterly Progress Report 36 (2034 Q2)	April 1 – June 30, 2034	July 30, 2034
Quarterly Progress Report 37 (2034 Q3)	July 1 – September 30, 2034	October 30, 2034
Quarterly Progress Report 38 (2034 Q4) *	October 1 – December 31, 2034	January 30, 2035
Quarterly Progress Report 39 (2035 Q1)	January 1 – March 31, 2035	April 30, 2035
Quarterly Progress Report 40 (2035 Q2)	April 1 – June 30, 2035	July 30, 2035
Quarterly Progress Report 41 (2035 Q3)	July 1 – September 30, 2035	October 30, 2035
Quarterly Progress Report 42 (2035 Q4) *	October 1 – December 31, 2035	January 30, 2036
Final Progress Report	August 1, 2025 – December 31, 2035	April 30, 2036

* Includes Community Based Organization Performance Report, if applicable, as described in Section 21, *Reporting Linked to Implementation Funding*

† Includes Milestone Funding Performance Report, if applicable, as described in Section 22, *Reporting Linked to Milestone Funding*

18. Financial Reports. The Recipient is required to record expenses in real-time as well as submit semi-annual expenditure Federal Financial Reports (FFRs)-SF-425s via the Payment Management System, as described in the Standard Terms and Conditions, Section 25(D), *Financial Reporting*, in accordance with the following schedule:

- a. **Semi-Annual Expenditure Federal Financial Report.** The Recipient shall complete Semi-Annual Expenditure Federal Financial Reports (SF-425 or FFR) in the Payment Management System no later than 30 days following the last day of the applicable semi-annual reporting period listed in Table 3. For specific directions on filing the

Semi-Annual Expenditure Federal Financial Report, see Standard Terms and Conditions, Section 25, *Reporting Requirements*.

- b. **Final Expenditure Federal Financial Report.** The Recipient shall submit the final Expenditure Federal Financial Report (SF-425 or FFR) in the Payment Management System no later than 120 days following the end of the Cooperative Agreement Period of Performance.

Table 3. *Due Dates for Submission of Semi-Annual FFRs and Final FFR*

Report Type	Reporting Period	Due Date
Semi-Annual FFR 1	August 1 – December 31, 2025	January 30, 2026
Semi-Annual FFR 2	January 1 – June 30, 2026	July 30, 2026
Semi-Annual FFR 3	July 1 – December 31, 2026	January 30, 2027
Semi-Annual FFR 4	January 1 – June 30, 2027	July 30, 2027
Semi-Annual FFR 5	July 1 – December 31, 2027	January 30, 2028
Semi-Annual FFR 6	January 1 – June 30, 2028	July 30, 2028
Semi-Annual FFR 7	July 1 – December 31, 2028	January 30, 2029
Semi-Annual FFR 8	January 1 – June 30, 2029	July 30, 2029
Semi-Annual FFR 9	July 1 – December 31, 2029	January 30, 2030
Semi-Annual FFR 10	January 1 – June 30, 2030	July 30, 2030
Semi-Annual FFR 11	July 1 – December 31, 2030	January 30, 2031
Semi-Annual FFR 12	January 1 – June 30, 2031	July 30, 2031
Semi-Annual FFR 13	July 1 – December 31, 2031	January 30, 2032
Semi-Annual FFR 14	January 1 – June 30, 2032	July 30, 2032
Semi-Annual FFR 15	July 1 – December 31, 2032	January 30, 2033
Semi-Annual FFR 16	January 1 – June 30, 2033	July 30, 2033
Semi-Annual FFR 17	July 1 – December 31, 2033	January 30, 2034
Semi-Annual FFR 18	January 1 – June 30, 2034	July 30, 2034
Semi-Annual FFR 19	July 1 – December 31, 2034	January 30, 2035
Semi-Annual FFR 20	January 1 – June 30, 2035	July 30, 2035
Semi-Annual FFR 21	July 1 – December 31, 2035	January 30, 2036
Final FFR	August 1, 2025 – December 31, 2035	April 30, 2036

PRIOR APPROVALS

- 19. Personnel Changes.** Key personnel changes require prior CMS approval. The Recipient must submit a personnel change request through submission of an amendment in GrantSolutions (based upon the applicable change request). The Recipient must notify the Project Officer and the CMS Grants Management Specialist within ten (10) calendar days before any key personnel changes affecting the award, including principal investigators/project director. Alternatively, if Recipient becomes aware of the key personnel changes less than ten (10) calendar days before the change is effective, then Recipient must notify CMS within ten (10) calendar days of when the Recipient becomes aware. See Standard Terms and Conditions, Section 11, *Prior Approval Requirements*, for further information.

There are two personnel request types:

- a. **Revision (NoA Other):** Changes to the Authorized Organizational Representative (AOR) or other key personnel changes besides the Project Director.
- b. **Revision (PI/PD):** Change in Project Director. See Standard Terms and Conditions, Section 11, *Prior Approval Requirements* for additional information.

20. Change in Scope. Prior approval from CMS is required for a change in scope if Recipient anticipates deviating from the original scope of work as described in the Application for which the Cooperative Agreement Award was awarded. If proposing changes, the Recipient must first consult with the Project Officer prior to submitting a formal amendment request in GrantSolutions. The formal request must include a detailed explanation for the change to the scope of work and be submitted as an amendment in GrantSolutions. If approved, the CMS Grants Management Officer will issue a revised NoA indicating approval. See Standard Terms and Conditions, Section 11, *Prior Approval Requirements*, for further information.

PROGRAM REQUIREMENTS AND MILESTONES

21. Reporting Linked to Implementation Funding. If the Recipient has been awarded Implementation Funding:

- a. For Implementation Funding to support required Model activities, the Recipient is required to comply with the reporting requirements specified in the Recipient's State Agreement with CMS.
- b. For Implementation Funding to support optional Model activities, in each Quarterly Progress Report the Recipient must include the reporting milestones approved in the Recipient's Application and describe the Recipient's progress with the implementation plan approved in the Recipient's Application.
- c. For Implementation Funding to support partnerships with community-based organizations (CBO) or nonprofit organizations:
 - i. In each Quarterly Progress Report, the Recipient must include an updated Partnership List that includes the following details of all funded CBOs and nonprofits:
 - A. Name
 - B. Mailing Address
 - C. Primary Contact
 - D. Primary Contact Email and Telephone
 - E. Amount of Award
 - ii. If a CBO is no longer a recipient of implementation funds (due to unsatisfactory performance, the conclusion of planned activities, or other issues), the Recipient must note and provide the reason for the conclusion of that relationship in the next Quarterly Progress Report.

- iii. In the Q4 Quarterly Progress Report for each year, the Recipient must submit a Community Based Organization Performance Report of all funded CBOs. The Community Based Organization Performance Report must adhere to the monitoring and reporting plan approved in the Recipient's Application and also include the following information:
 - A. The number of Beneficiaries with SCD in the State who received an identified service due to the funding provided through this award; and
 - B. The number of Beneficiaries with SCD in the State who received gene therapy who received an identified service due to the funding provided through this award.

22. Reporting Linked to Milestone Funding. If the Recipient has been awarded Milestone Funding:

- a. In each Quarterly Progress Report, the Recipient must describe the status of all Milestone Funding projects approved by CMS.
- b. The Recipient must submit a Milestone Funding Performance Report to verify satisfactory completion of the research project from the prior PY. The Milestone Funding Performance Report must be included in a Quarterly Progress Report no later than Q3 of each year and must include the following information:
 - i. Description of the research question(s) the project was designed to answer;
 - ii. Background on how the project is related to increasing access to SCD gene therapy or promoting receipt of multi-disciplinary, comprehensive care for Beneficiaries with SCD who are considering or receiving SCD gene therapy, per the patient care journey for SCD gene therapy;
 - iii. Description of the research methodology used in the project (including but not limited to: the study population, participant recruitment, any interventions implemented or studied, data collection, and data analysis);
 - iv. The number of participants included in the study;
 - v. Description and analysis of results;
 - vi. Limitations of the study;
 - vii. Identification and analysis of policy options for improvement;
 - viii. Explanation for how the Recipient intends to use the research findings to improve care for Model Beneficiaries;
 - ix. List of costs incurred to conduct the research project; and
 - x. The roles of any partner organizations in conducting the project.
- c. CMS reserves the right to change report components based on individual Recipients' project proposals and unforeseen circumstances that arise. CMS also reserves the right to revise the method of data submission to CMS based on new information or unforeseen circumstances that arise during Model implementation.

- d. If CMS approves the Recipient's Milestone Funding Performance Report and verifies that the Recipient has successfully completed the project, Milestone Funding associated with the project will be unrestricted and available for Recipient use. CMS may award partial funding for partial completion of a project. The Recipient may use unrestricted Milestone Funding only for cost-based reimbursement of their completed Milestone Funding projects.

23. Direct Services to Address Access Barriers. If included in the Recipient's approved Application, the Recipient may use Cooperative Agreement funding to pay for services and supports provided by community-based organizations (CBOs) related to childcare, housing, and nutrition supports, that meet the following scope, duration, and general limitations:

a. Scope.

- i. Services and supports must be for Beneficiaries in the State's Model population² meeting eligibility criteria for SCD gene therapy.
- ii. Services must be voluntary for Beneficiaries, and Beneficiaries may refuse or opt out of services at any time. States may not condition coverage of any standard Medicaid benefit or service on receipt of the services provided by a State through the Cooperative Agreement.
- iii. Services cannot already be provided by the State in accordance with the Medicaid assurance of transportation (which includes lodging and meals for the Beneficiary and caregiver for long-distance travel to medically necessary care).^{3,4}
- iv. Services must be necessary for directly accessing medical services required to complete the SCD gene therapy care journey.
- v. Housing and nutrition interventions must be evidence-based and medically appropriate for SCD Beneficiaries receiving gene therapy.
- vi. The scope of childcare services would be limited to payment/reimbursement for childcare (for the patient's children or the caregiver's children) by a licensed childcare provider while the patient is traveling overnight to/from treatment and during inpatient stays and outpatient visits.

b. Duration.

- i. Services and supports may be provided no earlier than: evaluation for gene therapy at a transplant center.
- ii. Services and supports may be provided no later than: the point at which the Beneficiary no longer needs weekly care from the transplant center.

² The Model population includes Medicaid and Medicaid expansion CHIP beneficiaries in fee-for-service and Medicaid managed care who do not have other coverage that is the primary payer for the Model gene therapies.

³ Social Security Act § 1902(a)(4)(A); *see also* 42 CFR § 431.53.

⁴ As described in 42 C.F.R. § 440.170(a), "'Transportation' includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a beneficiary." "Travel expenses' include... (ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and (iii) The cost of an attendant to accompany the beneficiary, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the beneficiary's family, salary."

c. General Limitations.

- i. States may not use Cooperative Agreement funding to pay for any benefits or services provided by the State's Medicaid program, or to duplicate or supplant any services already funded through federal, state, or local governments.
- ii. States may use Cooperative Agreement funding to sub-contract with community-based organizations (CBOs) to provide services that are neither Medicaid benefits nor services already funded through federal, state, or local governments.

24. Data Collection and Submissions. The Recipient must accurately collect and submit all required data in the form and manner requested by CMS and/or its contractors. The Recipient must use appropriate privacy and security protections for any data disclosed by CMS under this Model as specified in the Recipient's State Agreement with CMS.

25. Evaluation. CMS will conduct the CGT Access Model evaluation with the assistance of an independent contractor. The Recipient is an entity participating in the testing of a model under Section 1115A of the Act, and, as such, is required to collect and report such data as may be required by CMS, or its contractor(s), to carry out model evaluation, in accordance with 42 CFR § 403.1110(b). The Recipient is required to cooperate with the evaluation as specified in the Recipient's State Agreement with CMS. In addition, as a condition of receiving award funds, the Recipient is responsible for requiring and ensuring that model partners, including contractors and Subrecipients, participate in the model evaluation.

REMEDIAL ACTIONS, ENFORCEMENT ACTIONS, AND TERMINATION

26. Remedial Actions. CMS may impose additional specific award conditions as needed in accordance with 45 CFR 75.207, Specific award conditions, for Recipient's failure to comply and meet the deadlines stated in Section 21, *Reporting Linked to Implementation Funding*, and Section 22, *Reporting Linked to Milestone Funding*, of these Program Terms and Conditions. CMS will determine the specific remedial activities and actions. These activities and actions may include, but are not limited to:

- a. Requiring payments as reimbursements rather than advance payments;
- b. Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given period of performance (i.e., developing a plan to address non-compliance);
- c. Requiring additional, more detailed financial reports;
- d. Requiring additional project monitoring;
- e. Requiring the non-federal entity to obtain technical or management assistance; or
- f. Establishing additional prior approvals.

27. Enforcement Actions. CMS may take an enforcement action against the Recipient if CMS determines that the Recipient is non-compliant with the Terms and Conditions of Award. Failure to comply with the Terms and Conditions of Award includes, but is not limited to, the following:

- a. A documented pattern of non-cooperation with CMS, its contractors, the Department of Health and Human Services (HHS), or other federal agencies;
- b. Failure to receive and implement technical assistance provided by CMS or its contractors;
- c. Failure to comply with the Terms and Conditions of this Award, including the failure to meet any milestone or reporting requirement included in these Program Terms and Conditions;
- d. Failure to provide complete and accurate data, including failure to provide in a timely manner data or other information requested by CMS in a format accessible to CMS and its contractors;
- e. Failure to maintain valid authority to implement this Model as approved by CMS; or
- f. Improper use of Cooperative Agreement Award funds.

If the Recipient is non-compliant with the Terms and Conditions of Award, CMS may take an enforcement action against the Recipient. Potential enforcement actions may include, but are not limited to, restricting Cooperative Agreement Award funds through temporarily withholding cash payments, withholding further funds for the project, wholly or partially suspending or terminating the award, and other legal remedies as applicable, such as converting to the reimbursement payment method. See also Section 29, *Notification of Risk or Problems*.

CMS may amend these Program Terms and Conditions without the consent of the Recipient, as stated in these Program Terms and Conditions, for good cause, or as necessary to comply with applicable federal or state law, regulatory requirements, accreditation standards or licensing guidelines or rules. CMS must include with any such amendment an explanation of the reasons for the amendment. To the extent practicable, CMS must provide the Recipient with 30 days advance written notice of any unilateral amendment, which notice must specify the amendment's effective date.

28. Termination by CMS. CMS may terminate any award for material noncompliance. Material noncompliance includes, but is not limited to, violation of the terms and conditions of the award; failure to perform award activities in a satisfactory manner; improper management or use of award funds; or fraud, waste, abuse, mismanagement, or criminal activity.

- a. Section 1115A(b)(3)(B) requires the Secretary to terminate or modify the design and implementation of a model unless the Secretary determines after testing has begun that the model is expected to: improve quality of care without increasing Medicare, Medicaid and CHIP spending; reduce Medicare, Medicaid and CHIP spending without reducing quality of care; or improve quality of care and reduce spending for Medicare, Medicaid, and CHIP.
- b. If the Recipient's State Agreement with CMS is terminated, CMS will terminate this award, and all funding provided through this award not yet obligated must be returned to HHS.
- c. Recipient should refer to the Standard Terms and Conditions, Section 31, *Termination*, for additional termination specifications.

29. Notification of Risk or Problems. The Recipient shall immediately upon discovery⁵ notify the Project Officer and CMS Grants Management Specialist in writing of any significant problems or risks relating to the administrative, financial, and programmatic aspects of the award. Significant problems include, but are not limited to, adverse findings pursuant to Standard Terms and Conditions, Section 27, *Affirmative Duty to Track All Parties to the Award*, or issues or barriers that may cause the Recipient to miss Model milestones described in the Terms and Conditions of Award, or failure to implement the CGT Access Model as described in the NoA.

CMS may elect to allow the Recipient an opportunity to take appropriate remedies which may include the Recipient accepting specific award conditions, technical assistance, and/or adhering to a non-compliance action plan within a timeframe and manner determined by CMS. If the Recipient fails to meet the terms of any non-compliance action plan within the designated timeframe, CMS may terminate the Cooperative Agreement Award.

If the Recipient's actions endanger the public health and welfare, CMS may immediately terminate the Cooperative Agreement Award without the opportunity for corrective action.

The regulatory procedures that pertain to suspension and termination are stated in the Standard Terms and Conditions, Section 31, *Termination*. In the event of a conflict between the terms of this section and Section 31, *Termination* of the Standard Terms and Conditions, the terms of Section 31, *Termination* of the Standard Terms and Conditions shall prevail.

⁵ A problem is considered "discovered" as of the first day on which the problem is known, or reasonably should have been known, to the Recipient or to any employee, officer, or agent of the Recipient's business associate.

**Centers for Medicare & Medicaid Services
Standard¹ Grant/Cooperative Agreement² Terms and Conditions**

**These terms and conditions apply to all funded award actions issued on or after
August 1, 2025**

GENERAL

- 1. Recipient.** The Recipient named on the Notice of Award (NoA) in field #1 is the non-federal entity that receives a federal award directly from CMS to carry out an activity under this Federal program.

Recipients must comply with all terms and condition of their awards, including:

- (a) These Standard Terms and Conditions;
- (b) Recipient Specific Terms and Conditions, if applicable
- (c) Program Terms and Conditions
- (d) requirements of the authorizing statutes and implementing regulations for the program under which the award is funded
- (e) applicable requirements or limitations in appropriations acts
- (f) terms and conditions included in the HHS Grants Policy Statement ([HHS GPS - revised 4/16/2025.pdf](#)) in effect at the time of a new, noncompeting continuation, or renewal award, or supplemental award
- (g) the [HHS Administrative and National Policy Requirements](#)
- (h) applicable HHS grant regulations including [45 CFR 75](#), and portions of 2 CFR Part 200
- (i) any policies or requirements specific to the award; and
- (j) any requirements included in the Notice of Funding Opportunity (NOFO).

- 2. Acceptance of Application & Terms of Agreement.** By drawing or otherwise obtaining funds from the U.S. Department of Health and Human Services (DHHS) Payment Management System (PMS), the recipient:

- (a) acknowledges and accepts the terms and conditions of the award
- (b) is obligated to perform in accordance with the requirements of the award; and

¹ Standard Terms and Conditions include all possible grants administrative requirements for CMS awards. All standard terms and conditions apply unless the requirement is not applicable based on the project awarded. Recipients should contact their assigned Grants Management Specialist if they have questions about whether an administrative term and condition applies.

² A Cooperative Agreement is an alternative assistance instrument to be used in lieu of a grant whenever substantial Federal involvement with the recipient during performance is anticipated. The difference between grants and cooperative agreements is the degree of Federal programmatic involvement rather than the type of administrative requirements imposed. Therefore, statutes, regulations, policies, and the information contained in these Standard Terms and Conditions that are applicable to grants also apply to cooperative agreements, unless otherwise stated.

(c) certifies that proper financial management controls and accounting systems, to include personnel policies and procedures, have been established to adequately administer Federal awards and the funds drawn down.

Additionally, by accepting this award, including the obligation, expenditure, or drawdown of award funds, recipient certifies as follows:

By applying for or accepting federal funds from HHS, recipients certify compliance with all **federal antidiscrimination laws** and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

The Applicant hereby agrees that it will comply with **Title VI of the Civil Rights Act of 1964**, as amended (codified at 42 U.S.C. 2000d et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 80); **Section 504 of the Rehabilitation Act of 1973**, as amended (codified at 29 U.S.C. 794), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 84); **Title IX of the Education Amendments of 1972**, as amended (codified at 20 U.S.C. § 1681 et seq.) and all requirements imposed by or pursuant to the Regulation of the Department of the Health and Human Services (45 CFR Part 86); **The Age Discrimination Act of 1975**, as amended (codified at 42 U.S.C. § 6101 et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 91); and **Section 1557 of the Patient Protection and Affordable Care Act**, as amended (codified at 42 U.S.C. § 18116), and all requirements imposed by or pursuant to the Regulation of the Department of the Health and Human Services (45 CFR Part 92).

For Programs that could implicate **Title IX** (i.e., awards to or for school, colleges, universities, 4-H programs, non-governmental organization (NGO) programs, sports programs, and education-related awards to prisons or other detention facilities):

- Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.
- The above requirements are conditions of payment that go to the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any

prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.

Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

If the recipient cannot accept the terms, the recipient must notify the Grants Management Officer (GMO) within thirty (30) days of receipt of this award notice. Once an award is accepted by a recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

3. Funding for Recipients. All funding provided under this award must be used by the Recipient exclusively for the program referenced in the NoA and described in the NOFO and outlined in the Recipient's approved application. This includes any approved revisions, as applicable, made subsequent to the Recipient's approved application.

- Funds available to pay allowable costs during the period of performance include both Federal funds awarded and approved carryover balances.
- Federal award funds must supplement, not replace (supplant) non-federal funds. All recipients who receive awards under programs must ensure that federal funds do not supplant funds that have been budgeted for the same purpose through non-federal sources. Applicants or award recipients may be required to demonstrate and document that a reduction in non-federal resources occurred for reasons other than the receipt of expected receipt of federal funds.

4. Recipient Roles and Responsibilities.

- PI/PD: The PI/PD is the individual(s) employed and designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity, whether or not they receive salaries or compensation under the award.
- AOR: The AOR is an employee of the recipient and has authority to act for the organization. The AOR is responsible for meeting award requirements, properly managing the award, and providing oversight. The AOR's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- Key Personnel:
The PI/PD and other individuals who contribute to the programmatic development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award.

5. Uniform Administrative Requirements, Cost Principles, and Audit Requirements.

The NoA issued is subject to the administrative requirements, cost principles, and audit

requirements that govern Federal monies associated with this award, as applicable, in the Uniform Guidance – [2 Code of Federal Regulations \(CFR\) § 200](#) as codified by HHS at [45 CFR § 75](#).

Prior to October 1, 2025, this award is subject to 45 CFR 75 except for eight flexibilities from 2 CFR 200 adopted by HHS on October 1, 2024. After October 1, 2025, this award will be subject to any applicable provisions of 2 CFR 200 and 2 CFR 300.

The eight flexibilities from 2 CFR 200 are:

- **[2 CFR 200.1](#) – Modified Total Direct Cost Definition - Calculating Indirect Costs:** Increases from \$25,000 to \$50,000 the amount of subawards that recipients can apply to their indirect rate.
- **[2 CFR 200.1 and 200.313\(e\)\(1\)](#) - Equipment:** Increased thresholds for the purchase and disposition of equipment from \$5,000 to \$10,000.” Additionally, [2 CFR 200.313\(b\)](#) clarifies that Indian Tribes must use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- **[2 CFR 200.1 and 200.314\(a\)](#) - Unused Supplies:** Increases from \$5,000 to \$10,000 the purchase and disposition value of unused supplies.
- **[2 CFR 200.320](#) – Micro-purchase Threshold:** Increases the micro-purchase threshold to \$50,000.³
- **[2 CFR 200.333](#) - Fixed Amount Subawards:** Increases from \$250,000 to \$500,000 the amount of fixed amount subawards that a recipient may provide with prior written approval from the Federal agency.
- **[2 CFR 200.344](#) – Closeout:** Increases the time period for recipients to submit final reports in support of closeout of the award from 90 to 120 days.⁴
- **[2 CFR 200.414\(f\)](#) - De Minimis Indirect Cost Rate:** Increases indirect cost de minimis rate from 10% to 15%. Note that this does not apply to HHS Training or Foreign awards, for which HHS proposes to maintain a modification that caps the de minimis at 8%.
- **[2 CFR 200.501](#) - Single Audit:** Increased single or program-specific audit threshold from \$750,000 to \$1,000,000.

³ This provision has already been adopted by HHS by operation of law, Pub. L. No. 115-91, and OMB Memorandum 18-18. It is included to be clear that this regulation is in force for HHS.

⁴ This provision has already been adopted by HHS. See 88 FR 63591 (Sept. 15, 2023). It is included to be clear that this regulation is in force for HHS.

- 6. Fraud, Waste, and Abuse.** The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements as well as the [HHS OIG website](#). Information may also be submitted by [email](#) or by mail to:

Office of the Inspector General
U.S. Department of Health & Human Services
Attn: HOTLINE
330 Independence Ave., SW
Washington, DC 20201

Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous.

- 7. Medicare and Medicaid anti-kickback** statute is hereby incorporated by reference: [42 U.S.C. § 1320a-7b](#).
- 8. Payment.** The Division of Payment Management does not award grants. The issuance of grant awards and other financial assistance is the responsibility of the awarding agencies. Once an award is made, the funds are posted in recipient accounts established in the Payment Management System (PMS). Recipients may then access their funds by using the PMS funds request process.

When requesting payment, please include 2-3 sentences that clearly explains and justifies how the requested funds relate to your approved budget cost categories. Be sure to reference the appropriate category (e.g., Personnel, Travel, Contractual), and describe the activity associated with the expense. Do not include Personally Identifying Information (PII) in your request.

The PMS funds request process enables Recipients to request funds using a Personal Computer with an Internet connection. The funds are then delivered to the recipient via Electronic Funds Transfer (EFT). If you are a new grant recipient, register in PMS [here](#). If you need further help with that process, please contact the One-DHHS Help Desk via email at PMSSupport@psc.hhs.gov or call (877) 614-5533 for assistance.

- 9. GrantSolutions and email addresses.** Recipients must maintain an active account with GrantSolutions (GS) to communicate, receive, and obtain documentation from CMS. If the designated Recipient Authorized Organizational Representative (AOR) and Project Director (PD) do not already have accounts in GS, they must contact GS immediately upon receipt of award to complete a user account form. Any change in personnel with access to GS, must also be communicated to CMS and GS staff so that the key responsible individuals are current and correct within the GS system.
- 10. Reservation of Rights.** Nothing contained in this Award is intended or shall be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS OIG, or CMS of any right to institute any proceeding or

action against Recipient for violations of any statutes, rules or regulations administered by the Government, or to prevent or limit the rights of the Government to obtain relief under any other federal statutes or regulations, or on account of any violation of this Award or any other provision of law. The Award shall not be construed to bind any Government agency except CMS, and this Award binds CMS only to the extent provided herein, unless prohibited by law. The failure by CMS to require performance of any provision shall not affect CMS's right to require performance at any time thereafter, nor shall a waiver of any breach or default result in a waiver of the provision itself.

ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

11. Prior Approval Requirements. CMS anticipates that the recipient may need to modify the recipient's award budget or other aspects of its approved application during performance to accomplish the award's programmatic objectives. In general, recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes, provided that the changes still meet the statutory program requirements and the regulatory requirements under 45 CFR 75, as applicable.

Items that require prior approval (i.e. formal written approval) from the GMO, as stated in the Terms and Conditions of Award and HHS grant regulation 45 CFR 75, must be submitted in writing. Based on the nature, extent, and timing of the request, the GMO may approve, deny, or request additional material to further document and evaluate your request.

A Recipient must request approval of post-award changes to its award through submission of an amendment in GS (based upon the applicable change request). Only an amended NoA signed by the GMO is considered valid approval. Verbal authorization is not approval and is not binding on CMS. Recipients who proceed without prior approval, do so at their own risk.

Amendment Type guidance:

- If a budget revision/change request impacts more than one budget category, utilize Revision (Budget) amendment type.
- If budget revision change request only impacts one budget category, utilize Revision (NoA Other) amendment type.
- If the change requested does not match a possible amendment type from the selection list in GS, utilize Revision (NoA Other) amendment type.

Prior approval is **required** for but is not limited to:

- Changes in Key Personnel and Level of Effort,
- Budget Revisions (see also Standard Term and Condition #11. *Revision of Budget and Program Plans*),
- Changes in Scope,
- Carryover Requests,
- Travel Requests (as detailed below),

- For attendance at any conference⁵, including those sponsored by CMS, recipients must submit a detailed breakdown of costs associated with attending the conference for prior written approval. All costs must be individually itemized. This breakdown should include all costs associated with travel to the conference and a brief narrative explaining the program related purpose/how attending the conference will further the objectives of the program.
- **Note:** All federally funded travel must be tracked through a travel log which includes: traveler/position, destination, length of stay, mileage, per diem, reason for the trip, airfare, and any other reimbursable expenses. Recipients must also consult and comply with requirements outlined under [45 CFR §75.474, Travel Costs](#).
- Purchase of Technology
 - Purchase of technology items (both those classified as equipment and those classified as supplies), over and above that which is already approved in the budget must be approved by the GMO (regardless of acquisition cost).
 - **Note:** All technology items, regardless of classification as equipment or supply must still be individually tagged and recorded in an equipment/technology data. This database should include any information necessary to properly identify and locate the item. For example, serial # and location of equipment (e.g. laptops, tablets, etc.).
- No Cost Extensions;
- Lifting of Funding Restrictions;
- Removal of Non-Compliance Plans;
- Any costs to support rearrangement, alteration, reconversion, or capital expenditures (refer to 45 CFR §§75.439 and 75.462).

Activities that require prior approval are further detailed in HHS grant regulation 45 CFR § 307 and §474 and the HHS Grant Policy Statement.

12. Revision of Budget and Program Plans. Recipients must consult and comply with requirements outlined under 45 CFR §75.308, *Revision of budget and program plans*. Please note that CMS is not waiving any prior approval requirements outlined in this section of the regulation or as stated in these Standard Terms and Conditions. Additionally, in accordance with §75.308(e), CMS requires prior approval for budget revisions where the transfer of funds among direct cost categories or programs, functions and activities in which the Federal share of the project exceeds the Simplified Acquisition Threshold (\$250,000) and the **cumulative amount** of such transfers exceeds or is expected to exceed **10 percent** of the

⁵ OMB Memorandum M-12-12 employs, and HHS has adopted the following definition for a conference from the Federal Travel Regulation (FTR): A “conference” is defined as “[a] meeting, retreat, seminar, symposium or event that involves attendee travel. The term ‘conference’ also applies to training activities that are considered to be conferences under 5 CFR 410.404.”

total budget as last approved. CMS cannot permit a transfer that would cause any Federal appropriation to be used for purposes other than those consistent with the appropriation.

- Recipients with total costs below the simplified acquisition threshold may transfer up to 25% of the total current budget approved within and between approved direct cost categories per budget period without prior approval.
- CMS must review and approve rebudgeting among direct cost categories or programs, functions and activities of 25% or more of total costs of the last approved budget period (for the current budget period) for all federal awards.
- Once the rebudgeting threshold is reached, the recipient must request prior approval for all additional changes during that budget period.

13. Conflict of Interest Policies. Recipient must comply with the conflict-of-interest policy requirements outlined in **Attachment A** to these Standard Terms and Conditions. See also [45 CFR §75.112](#).

14. Bankruptcy. If Recipient or one of its subrecipients enters bankruptcy proceedings, whether voluntary or involuntary, the Recipient agrees to provide written notice of the bankruptcy to the CMS Grants Management Specialist and CMS Project Officer (PO) within five (5) days of initiation of the proceedings. This notice shall include the date on which the bankruptcy petition was filed, the identity of the court in which the bankruptcy petition was filed, a copy of any and all of the legal pleadings, and a listing of Government grant and cooperative agreement numbers and grant offices for all Government grants and cooperative agreements against which final payment has not been made.

15. Prohibition on certain telecommunications and video surveillance services or equipment. [2 CFR 200.216](#) is incorporated herein by reference.

16. Human Subjects Protection. If applicable to Recipient's program, the Recipient bears ultimate responsibility for protecting human subjects under the award, including human subjects at all sites, and for ensuring that a Federal-wide Assurance (FWA) approved by the Office for Human Research Protections (OHRP) and certification of Institutional Review Board (IRB) review and approval have been obtained before human subjects research can be conducted at each collaborating site. For more information about OHRP, FWA, and IRBs, click [here](#).

Recipients may not draw funds from PMS, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an OHRP-approved assurance and IRB approval consistent with 45 CFR Part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges under grants and cooperative agreements unless such costs are not covered by the organization's indirect cost rate.

HHS requires Recipients and others involved in grant/cooperative agreement-supported research to take appropriate actions to protect the confidentiality of information about and the privacy of individuals participating in the research. Recipients, subrecipients, Investigators, IRBs, and other appropriate entities must ensure that policies and procedures are in place to

protect identifying information and must oversee compliance with those policies and procedures.

17. Privacy and Security of Health Information. The Recipient shall put all appropriate regulatory, administrative, technical, and physical safeguards in place before applicable program activities begin to protect the privacy and security of individually identifiable health information. In doing so, regardless of whether it is a covered entity (CE) or business associate (BA) as those terms are defined under the HIPAA Privacy Rule, the Recipient shall ensure its own and its subrecipients' and contractors' policies and procedures are at least as stringent (i.e., protective of privacy) as those governing the use and disclosure of protected health information by HIPAA CEs and their BAs under 45 CFR parts 160 and 164. The Recipient and its subrecipients should consult with their own counsel and refer to the [HIPAA guidance materials](#) for further information about the requirements in 45 CFR Parts 160 and 164.

18. Employee Whistleblower Protections. Federal law mandates that all Federal contractors, subcontractors, recipients, subrecipients, or personal services contractors, must inform their employees in writing of the rights and remedies provided under this section, in the predominant native language of the workforce. For more information click [here](#).

19. Mandatory Disclosures. Consistent with 45 CFR §75.113, applicants and recipients must disclose in a timely manner, in writing to CMS, with a copy to the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Additionally, subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to CMS and to the HHS OIG at the following addresses:

U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
Office of Acquisition and Grants Management
Attn: Director, Division of Grants Management, Mandatory Grant Disclosures
7500 Security Blvd, Mail Stop B3-30-03
Baltimore, MD 21244-1850

Materials should also be scanned and emailed to your Grants Management Specialist.

AND

U.S. Department of Health & Human Services
Office of Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW, Cohen Building
Room 5527
Washington, DC 20201

Fax: (202) 205-0604 (Include “Mandatory Grant Disclosures” in subject line) or
Email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 45 CFR §75.371, *Remedies for noncompliance*, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

20. Suspension and Debarment Regulations. [45 CFR §75.213](#) is incorporated herein by reference.

21. FY 2025 Appropriations Provision. The Department of Health and Human Services (HHS), operates under the Full-Year Continuing Appropriations and Extensions Act, 2025 ([Public Law 119-4](#)), signed on March 15, 2025. This Act (CR) continues government operations through September 30, 2025, at the Fiscal Year (FY) 2024 enacted level.

The Full-Year Continuing Appropriations and Extensions Act, 2025 ([Public Law 119-4](#)) applies the terms and conditions of the Consolidated Appropriations Act, 2024. Recipients must still otherwise review and comply with applicable General Provisions under Division D, Title II, for the DHHS (see General Provisions 202-241) and applicable General Provisions under Title V (see General Provisions 501-531 for the Departments of Labor, Health and Human Services and Education) included within the Appropriations Law ([H.R.2882](#), for the Departments of Labor, Health and Human Services, and Education). These provisions may apply to all recipients of HHS federal funding OR may apply directly to recipients of federal funding from one or more HHS agencies.

Salary Limitations: As is noted under Division D, Title II, General Provisions, Section 202, none of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II. This salary cap applies to direct salaries. Recipients may pay salaries at a rate higher than the Executive Level II if the amount beyond the HHS salary cap is paid with non-HHS funds. Since the Executive Level II rate and HHS Appropriations Act citation changes each year, HHS refers to the most recent information posted on the Office of Personnel Management (OPM) website at [2025 Executive Level II Pay Scale](#).

22. Cybersecurity. If award funding involves ongoing and consistent access to HHS owned or operated information or operational technology systems, and the handling of personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award, then recipients or subrecipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data. Recipient cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework](#), to protect HHS systems and data:

- Identify:
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
- Protect:
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\)](#) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
- Detect:
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
- Respond:
 - Develop an incident response plan. See [Incident-Response-Plan-Basics 508c.pdf \(cisa.gov\)](#) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
- Recover:
 - Investigate incidents and plug any security gaps identified.

COST PRINCIPLES

CMS recipients must comply with the cost principles set forth in HHS regulations at 45 CFR Part 75, Subpart E with the following exceptions:

- (1) the eight adopted provisions of 2 CFR 200 identified in Standard Term and Condition #5
- (2) the cost principles for Hospitals subject to Appendix IX to Part 75, and

(3) the cost principles for commercial (for-profit) organizations subject to 48 CFR subpart 31.2⁶.

Guidelines for determining direct and indirect (F&A) costs charged to Federal awards are provided in 45 CFR §§75.412 to 75.419. Requirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans are contained in Appendices III-Appendix IX to Part 75.

For-profit entities which receive the preponderance of their federal awards from HHS may contact the Division of [Financial Advisory Services \(DFAS\), Indirect Cost Branch](#), to negotiate an indirect cost rate. Otherwise, for-profit organizations are limited to the 15% de minimis rate in accordance with 2 CFR [§ 200.414\(f\)](#).

23. Prohibited Uses of Grant or Cooperative Agreement Funds. The following list contains costs that are unallowable for all CMS programs. Recipient should consult the Program Terms and Conditions for other prohibited costs specific to the grant or cooperative agreement program.

- Pre-award costs.
- Meeting matching requirements for any other federal funds or local entities.
- Services, equipment, or supports that are the legal responsibility of another party under federal, state, or tribal law such as vocational rehabilitation or education services. Such legal responsibilities include, but are not limited to, modifications of a workplace or other reasonable accommodations that are a specific obligation of the employer or other party.
- Goods or services not allocable to the approved project.
- Supplanting existing state, local, tribal, or private funding of infrastructure or services, such as staff salaries.
- Construction.
- Capital expenditures for improvements to land, buildings, or equipment that materially increase their value or useful life as a direct cost except with the prior written approval.
- The cost of independent research and development, including their proportionate share of indirect costs in accordance with 45 CFR §75.476.
- Profit to any recipient even if the recipient is a commercial (for-profit) organization. Profit is any amount in excess of allowable direct and indirect costs.
- Funds related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body.
 - Per 45 CFR §75.215, Recipients are subject to the restrictions on lobbying

⁶ There are no cost principles specifically applicable to grants to for-profit organizations. Therefore, the cost principles for commercial organizations set forth in the FAR (48 CFR subpart 31.2) generally are used to determine allowable costs under CMS grants to for-profit organizations. As provided in those cost principles, [allowable travel costs](#) may not exceed those established by the FTR. The cost principles in 45 CFR 75, Appendix IX, determine allowable costs under CMS grants to proprietary hospitals.

as set forth in 45 CFR §93.

- Recipients must also comply with lobbying restrictions outlined in the applicable Appropriations Law.
- Other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government, funding awarded under this NOFO may not be used for:
 - Paying the salary or expenses of any grant recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or executive order proposed or pending before the Congress or any state government, state legislature, or local legislature or legislative body.
 - Lobbying, but awardees can lobby at their own expense if they can segregate federal funds from other financial resources used for lobbying.
- Certain telecommunications and video surveillance equipment. See 2 CFR 200.216.
- Costs of promotional items and memorabilia, including models, gifts, and souvenirs;
- Costs of advertising and public relations designed solely to promote the non-Federal entity.
- Meals unless in limited circumstances such as:
 - Subjects and patients under study;
 - Where specifically approved as part of the project or program activity (not recipient specific), e.g., in programs providing children's services; and
 - As part of a per diem or subsistence allowance provided in conjunction with allowable travel.

For guidance on some types of costs that we restrict or do not allow, see 45 CFR part 75, General Provisions for Selected Items of Cost.

POST AWARD MONITORING AND REPORTING

24. Continued funding is contingent on satisfactory progress, compliance with the terms and conditions, program authority, and the availability of funds. The NoA identifies the period of performance, which may include multiple 12-month budget periods. If a period of performance is comprised of multiple budget periods, the recipient must submit a non-competing continuation application each year as a prerequisite to continued funding.

Recipients must demonstrate satisfactory performance during the previous funding cycle(s) to be issued additional year funding; or, in the case of multi-year awards where all funding is issued in the first year, to ensure continued access to funding. Recipients should refer to the NOFO and Program Terms and Conditions for additional information on satisfactory progress.

Additionally, as is noted in 45 CFR Part 75, CMS annually conducts a review of risks posed by applicants prior to award (recipients should review the factors in their entirety at §75.205).

At-risk recipients, including those which do not comply with reporting requirements or have outstanding audit findings, may not receive a non-competing continuation award.

Alternatively, recipients could receive decreased funding, or their award could be terminated in accordance with [45 CFR 75.372 \(Termination\)](#) if they are non-compliant with the terms and conditions of award. See Standard Term and Condition #31. *Termination* for provisions effective October 1, 2025.

25. Reporting Requirements. Recipients must comply with the reporting requirements outlined in the Standard **and** Program Terms and Conditions of award. The general information and guidance for financial and programmatic reporting provided below supplements the specifics included in the Program Terms and Conditions.

A. PROJECT AND DATA INTEGRITY

Recipient must protect the confidentiality of all project-related information that includes personally identifying information.

The Recipient shall assume responsibility for the accuracy and completeness of the information contained in all technical documents and reports submitted. The CMS PO shall not direct the interpretation of the data used in preparing these documents or reports.

At any phase in the project, including the project's conclusion, the Recipient, if requested by the CMS PO, must deliver to CMS materials, systems, or other items used, developed, refined or enhanced in the course of, or under the award. The Recipient agrees that CMS must have a royalty-free, nonexclusive and irrevocable license to reproduce, publish, or otherwise use and authorize others to use the items for Federal government purposes.

B. SYSTEM OF AWARD MANAGEMENT (SAM) AND UNIVERSAL ENTITY IDENTIFIER (UEI) REQUIREMENTS

This award is subject to the requirements of [2 CFR part 25, Appendix A](#) which is specifically incorporated herein by reference. Recipient must maintain current information in SAM, at all times when an award is active or if there is an application pending review. Recipient must review and update the information **at least once a year** after the initial registration to remain active, and more frequently if required by changes in the information. This requirement flows down to subrecipients and contractors under awards or subawards. As part of its SAM registration and renewal process,

Recipient must also complete or update its **Responsibility/Qualification (R/Q)** reporting to reflect information about its civil, criminal, or administrative proceedings.

Applicants/recipients must answer "Yes" to question #1 (shown below) of the Proceedings question in SAM.gov to view and answer all relevant questions.

- Is your business or organization, as represented by the Unique Entity ID on this entity registration, responding to a Federal procurement opportunity that contains the provision at FAR 52.209-7, subject to the clause in FAR 52.209-9 in a current Federal

contract, **or** applying for a Federal grant opportunity which contains the award term and condition described in 2 C.F.R. 200 Appendix XII?

C. SUBAWARD REPORTING AND EXECUTIVE COMPENSATION (FFATA)

This award is subject to the reporting requirements of the Federal Funding Accountability and Transparency Act of 2006 (Public Law 109-282), as implemented by [2 CFR Part 170](#). Requirements include:

- A. First tier subaward reporting of \$30,000 or more in federal funds. Due no later than 30 days after issuance of subaward.
- B. Executive compensation reporting, if required, as referenced in 2 CFR Part 170. Due no later than 30 days after issuance of subaward.

D. FINANCIAL REPORTING

HHS recipients must record recipient expenses in real-time as well as submit quarterly, semi-annual, or annual expenditure Federal Financial Reports (FFRs) as described below and stipulated in the Program Terms and Conditions of Award. Instructions on how to complete the FFR can be found [here](#). (after logging onto PMS)

- Quarterly and semi-annual expenditure reports are due no later than 30 days following the applicable period.
- Annual expenditure FFRs are due no later than 90 days following the applicable budget period end date or 12-month period for multi-year budget periods.
- Final FFRs are due no later than 120 days following the period of performance end date.
 - The final FFR must show cumulative expenditures under the award and any unobligated balance of federal funds and as appropriate, all other parts of the form must be completed.
 - Additionally, Recipient must liquidate all obligations incurred under the award not later than 120 days after the end of the period of performance. This deadline may be extended with prior written approval from the CMS Grants Management Specialist.

E. PROGRAMMATIC REPORTING

See [2 CFR §200.301](#), *Performance Measurement*, and Program Terms and Conditions for specific details on required information.

Submission of Progress Reports to PMS

Recipients must submit progress reports to GrantSolutions via the Performance Progress Report (PPR) module.

Recipients with the following roles can view, edit, and electronically submit the PPR:

- Recipient’s Authorized Organizational Representative (AOR)
- Principal Investigator/Program Director (PI/PD) assigned to the Award

The CMS Project Officer will either accept or return the PPR to the Recipient for additional information or clarification. The cooperative agreement will not be considered complete and in accordance with the applicable terms and conditions of award until all required reports have been accepted by the CMS Project Officer.

F. STEVENS AMENDMENT

When issuing statements, press releases, publications, requests for proposals, bid solicitations, and other documents – such as toolkits, resource guides, websites, and presentations – describing the projects or programs funded in whole or in part with HHS funds, the recipient must clearly state:

- (1) the percentage and dollar amount of the total costs of the program or project funded with Federal money; and
- (2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

Acknowledgement of Support

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement (see immediately below).

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This **[project/publication/program/website, etc.] [is/was]** supported by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **\$XX** with 100 percent funded by CMS/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CMS/HHS, or the U.S. Government.

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This **[project/publication/program/website, etc.] [is/was]** supported by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **\$XX** with **XX** percentage funded by CMS/HHS and **\$XX** amount and **XX** percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CMS/HHS, or the U.S. Government.

- (a) **Review by CMS.** Recipient shall submit the following to the CMS PO for review and comment unless specified otherwise in the Program Terms and Conditions:
- (i) At least 30 days prior to its release:
 - publications that report results from or describe information obtained through this award.
 - any external formal presentation of any report or statistical or analytical material based on information obtained through this award. Formal presentation includes papers, articles, professional publication, speeches, and testimony.
 - external presentation-related material, such as abstracts, power point presentations or other slide decks, posters, and videos.
 - all public materials specific to the program including but not limited to, brochures, recruitment materials, informational materials, advertisements, website copy, website pages, videos, and op-ed articles.
 - (ii) At least 7 days prior to release:
 - any press release or media advisory concerning the outcome of activities supported through this award.
 - all media interviews, media requests, releases of information, filming, and broadcasts.
- (b) For 1 year after completion of the project, the Recipient shall continue to submit for review and comment all publications, presentations, and communications resulting from this award or based on information obtained through this award, including papers, articles, professional publications, power point presentations, posters, speeches, announcements, and testimony in any format, including digital technology.
- (c) It is the policy of the DHHS that the Recipient must communicate to CMS how the dollar amounts and funding percentages are calculated, including whether or not indirect costs have been incorporated. Recipient must submit this information to CMS for review and comment for each applicable type of result/accomplishment according to the same timeline schedule outlined in 17(a).
- (d) Specifically excluded from the review and comment process are internal presentations, information discussions, in general, class lectures, and informal meetings and conversations with community leaders. However, if such a presentation or slide deck is later re-purposed for a public event, it will need to be submitted in advance for CMS review.
- (e) One copy of each publication resulting from work performed under an HHS grant-supported project must accompany the final progress report.

G. USE OF DATA AND WORK PRODUCTS (REPORTING)

At any phase of the project, including the project's conclusion, the Recipient, if so requested by the CMS PO, shall submit copies of analytic data file(s) with appropriate documentation, representing the data developed/used in end-product analyses generated under the award. The analytic file(s) may include primary data collected, acquired or generated under the award and/or data furnished by CMS. The content, format, documentation, and schedule for production of the data file(s) will be agreed upon by the Principal Investigator/Project Director (PI/PD) and the CMS PO. The negotiated format(s) could include both file(s) that

would be limited to CMS's internal use and file(s) that CMS could make available to the general public.

All data provided by CMS will be used for the research described in this grant/cooperative agreement award only and in connection with the Recipient's performance of its obligations and rights under this program. Recipient has an obligation to collect and secure data for future monitoring by CMS. The Recipient will return any data provided by CMS or copies of data at the conclusion of the project. All proprietary information and technology of the Recipient are and shall remain the sole property of the Recipient.

If the PI/PD determines through this research that a significant new finding has been developed, he/she will communicate it to the CMS PO before formal dissemination to the general public. The Recipient shall notify CMS of research conducted for publication.

H. ANNUAL PROPERTY REPORTING.

[45 CFR §75.319, *Federally-owned and exempt property*](#), is incorporated herein by reference. Recipient must submit annually an inventory listing of Federally-owned property in its custody to CMS.

I. PATENTS AND INVENTIONS

In accordance with [45 CFR §75.322\(c\)](#), all Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401. If applicable, Recipients must report any inventions on an annual basis using the non-competing continuation application or annual progress report for multi-year budget periods.

A Final Invention Statement and Certification ([Form HHS 568](#)) must be completed and submitted within 120 days following the expiration or termination of a grant or cooperative agreement.

- The Statement must include all inventions which were conceived or first actually reduced to practice under the grant or award, from the original effective date of support through the date of completion or termination.
- The Statement shall include any inventions reported previously for grants and cooperative agreements as part of a non-competing continuation application or annual progress report.
- Recipients must also provide details about all inventions that have been licensed but not patented and include details on income resulting from HHS-funded inventions and patents.

Unpatented research products or resources—research tools—may be made available through licensing to vendors or other investigators. Income earned from any resulting fees must be treated as program income. This reporting requirement is applicable to grants and cooperative agreements issued by the U.S. DHHS in support of research and research-related activities. For further guidance, please see the HHS GPS: *Patents and Inventions* and *Inventions Reporting*.

J. AUDIT REPORTING (SEE 2 CFR 200.501).

A non-Federal entity that expends \$1,000,000 or more during the non-Federal entity's FY in Federal awards must have a single or program-specific audit conducted for that year and submit an audit reporting package to the Federal Audit Clearinghouse (FAC). HHS grant awarding agencies are required to ensure that single or program-specific audits are completed and reported by recipients within nine months after the end of the audit period (recipient FY end date).

For questions and information concerning the FAC submission process, please contact the FAC (entity which assists Federal cognizant and oversight agencies in obtaining audit data and reporting packages) at 888-222-9907 or click [here](#).

For-profits including for-profit hospitals) should consult 45 CFR §75.216 for limitations on profit and program income. Consult 2 CFR 200.501(i) and your Grants Management Specialist.

Audits for for-profit organizations with HHS programs must be sent to:

- the HHS Audit Resolution Division (ARD) via email at For-Profit_Audit@hhs.gov
- copy to: CMS KC_OIG_Audit <KC_OIG_Audit@cms.hhs.gov>
- copy to the Grants Management Specialist identified in Federal Awarding Agency box #9 on the NoA.

All for-profit organization audit submission questions should be sent to ARD via email at AuditResolution@hhs.gov.

Do not send audits for commercial organizations (for-profits) to the FAC.

SUBRECIPIENT PASS-THROUGH REQUIREMENTS

The recipient can provide a portion of the direct award to other organizations, called subrecipients, to accomplish the goals and objectives of the award. In this case, the recipient becomes a pass-through entity and the subrecipient's award is called a subaward. As a recipient, you must ensure the applicable general terms and conditions stated in this document flow down to subrecipients.

The recipient is **completely** legally and financially responsible for **all** aspects of this award including funds provided to subrecipients, in accordance with 45 CFR §75.351 –75.352, Subrecipient monitoring and management.

26. Subaward Reporting. Refer to Standard Term and Condition, 25. (C) *Subaward Reporting and Executive Compensation (FFATA)*.

27. Affirmative Duty to Track All Parties to the Award. Recipient must at a minimum regularly track all subrecipients, including subrecipient key personnel as well as subcontractors in SAM.gov.

As provided in 2 CFR part 180 and implemented in 2 CFR part 376, the recipient must check SAM.gov as follows to ensure that it does not make a subaward to an entity that is debarred, suspended, or ineligible:

- For all first-tier subawards regardless of potential value. Agencies must also require first tier- subrecipients and lower-tier subrecipients to check SAM.gov and
- For all first-tier procurement contracts with a value of \$25,000 or more and all lower tiers of subcontracts under covered non-procurement transactions (2 CFR 376.220).

The purpose of this affirmative duty is to track all parties that include health care, commercial, non-profit, and other people and entities to report immediately to the CMS PO and Grants Management Specialist those that cannot participate in federal programs or receive federal funds. The Recipient cannot have any persons or entities on the award that cannot participate in federal programs or receive federal funds. If any of these systems are not publicly available, then the Recipient must comply with the purpose and intent of this requirement using a process that meets at least the level of scrutiny provided by these databases.

The Recipient shall provide the CMS PO and Grants Management Specialist with the National Provider Identifier (NPI), Tax ID, and EIN, as applicable, of all Key Personnel and/or entities to the award that may include subrecipients. This list shall be provided to CMS as a Grant Note in GS within **thirty (30) days** from the start of the award and must be maintained in real time throughout the award.

28. Pass Through Entities, Subrecipients, and Contractors. [45 CFR §75.351, Subrecipient and contractor determinations](#), and [45 CFR §75.352, Requirements for pass-through entities](#), are incorporated herein by reference.

Recipient must monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved.

29. Subrecipient Equal Treatment. [45 CFR Part 87](#) is incorporated herein by reference.

REMEDIES FOR NONCOMPLIANCE

30. Non-compliance. [45 CFR §75.207, Specific award conditions](#), and [45 CFR §75.371, Remedies for noncompliance](#), are incorporated herein by reference.

31. Termination. Prior to October 1, 2025, this award is subject to [45 CFR §75.372, Termination](#), incorporated herein by reference.

CMS and the recipient may terminate the award through mutual agreement, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated. Alternatively, the recipient may notify CMS, or the pass-through entity, setting forth the reasons for such termination, the effective date, and in the case of partial termination, the portion to be terminated.

CMS may terminate any award for material noncompliance. Material noncompliance includes, but is not limited to, violation of the terms and conditions of the award; failure to perform award activities in a satisfactory manner; improper management or use of award funds; or fraud, waste, abuse, mismanagement, or criminal activity.

Starting on October 1, 2025, this award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and a decision by the agency that the award continues to effectuate program goals or agency priorities.

CLOSEOUT

32. Withdrawal. If the Recipient decides to withdraw from this award prior to the end of the period of performance, it must provide written notification (both hard copy and via email) to the CMS Grants Management Specialist at least fifteen (15) days in advance of the date of official withdrawal and termination of these terms. The letter must be signed by the AOR and other appropriate individuals with authority. CMS will not be liable for any withdrawal close-out costs that are borne by the Recipient. Recipients have three (3) days to return all unused grant funds.

33. Disposition of Federally Owned Property, Equipment, and Residual Unused Supplies. Upon completion (or early termination) of a project, Recipient must take appropriate disposition actions.

Recipient must complete and submit the **SF-428 Cover Letter, SF-428-B Tangible Personal Property Report, Final Report**. The Tangible Personal Property Report (SF-428) is a standard form to be used by awarding agencies to collect information related to tangible personal property when required by a Federal financial assistance award. This form:

- allows recipients to request specific disposition of federally-owned property and acquired equipment.
- provides a means for calculating and transmitting appropriate compensation to CMS for residual unused supplies.

As noted in 1.b of this report, if your agency is in possession of Federally-owned property or acquired equipment (defined as nonexpendable personal property with an acquisition cost of \$10,000 or more under the award), you must also submit a **SF-428-S, Supplemental Sheet**,

that lists and reports on all Federally-owned or acquired equipment under the specific grant or cooperative agreement award. If there is no tangible personal property to report, select “d.” in section 1 of the SF-428-B and indicate “none of the above.”

Recipient must request specific disposition instructions from CMS if the Recipient has federally-owned property. Otherwise, disposition instructions are here [§ 200.313 Equipment](#) [§ 200.314 Supplies.](#)

34. Records Retention. [45 CFR §75.361](#) is incorporated herein by reference.

**Centers for Medicare & Medicaid Services
Standard Grant/Cooperative Agreement Terms and Conditions
Attachment A**

Conflict of Interest Policy

CMS requires recipients to establish safeguards to prevent employees, officers, or agents of the non-Federal entity such as consultants, contractors, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial or other gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, CMS does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State, local, and tribal laws and regulations, and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas for governmental organizations as political participation and bribery.

Definitions:

"Principal Investigator/Project Director (PI/PD)" means the individual(s) designated by the recipient to direct the project or program being supported by the grant. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity. This designation also includes co-principal investigators/co-project directors, and any other person at the organization who is responsible for the design, conduct, or reporting of grant activities funded or proposed for funding by CMS.

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

This term does not include:

- a. salary, royalties or other remuneration from the applicant organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for the PI/PD and the PI/PD's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair

market value, and does not represent more than a 5% ownership interest in any single entity; or

e. salary, royalties or other payments that, when aggregated for the PI/PD and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

The term "or other interest" means a non-financial benefit which results in a potential or real conflict of interest. The potential or real conflict of interest poses the same possible harms received from a financial conflict of interest such as bias due to personal gain. Such benefits may be received from a tangible or intangible personal benefit.

"Organizational conflicts of interest" means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.

"Responsible representative" means the individual(s), named by the applicant/recipient organization, who is authorized to act on behalf of the applicant/recipient and to assume responsibility for the obligations imposed by federal laws, regulations, requirements, and conditions that apply to CMS grant awards.

Requirements:

The majority of CMS' grant programs are not supported by Public Health Service (PHS) funding; therefore, CMS is not subject to the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research." Notwithstanding, CMS expects grant activities (including research activities) to be free from bias by any conflicting interest of the PI/PD and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of grant activities which may include collaborators or consultants.

Recipient's conflict of interest policies must reflect the following:

- Have a written and enforced administrative process to eliminate conflicting financial or other interests with respect to CMS grant/cooperative agreement funds awarded. This process should ensure:
 - The merits for determining a conflict of interest are clearly articulated in writing – i.e., the assigned reviewer(s) can reasonably determine that a significant or other interest could directly and significantly affect the design, conduct, or reporting of CMS-funded grant activities. This process should be inclusive of the appearance of such conflicts.
 - Each PI/PD discloses to a responsible representative of the Recipient all significant financial and/or other interests including personal relationships of the PI/PD (for example, PI/PD's spouse, dependent children, etc.): (i) that would reasonably appear to be affected by the grant activities funded or proposed for

- funding by CMS; or (ii) in entities whose financial or other interests would reasonably appear to be affected by such activities.
 - One or more objective persons (1) reviews the potential conflict of interest; (2) determines whether a potential (appearance of) or real conflict of interest exists; and (3) establishes what conditions, or restrictions, should be imposed to eliminate the conflict of interest.
 - This information is conveyed to the Responsible Representative for the organization who is designated to act on behalf of the applicable CMS award.
- Prior to expending funds under a new CMS award, the Responsible Representative must inform the applicable CMS Grants Management Specialist and Project Officer of any real or potential conflict of interest. The report must detail Recipient's plan to eliminate the conflict prior to spending CMS funding on the activities in question.
- Require that similar reports for subsequently identified conflicts be made within 30 days of identifying them. Funding for those specific activities should cease until the aforementioned steps are completed.
- Require that continual updates be made for any real or potential conflicts of interest not fully resolved. Recipient must make additional information available to the CMS Grants Management Specialist and Project Officer, upon request, as to how it is handling (or had handled) the real or potential conflict of interest.
- Recipients must maintain records of all disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any CMS action involving those records, whichever is longer.
- The Recipient's policy must include adequate enforcement mechanisms and provide for sanctions where appropriate.

Recipient may resolve such conflicts of interest through one or more of the following options outlined below. This is not an exhaustive list and Recipient may pursue other remedies.

- Modification of approved project to remove potential or real conflict of interest.
- Termination of agreement or other services that create potential or real conflict of interest.
- Removal of individuals with potential or real conflict of interest.
- Severance of relationships that create potential or real conflicts of interest.
- Divestiture of significant financial interests.

Recipient must ensure that CMS award funds are administered in accordance with conflict-of-interest policies that meet, at a minimum, the standards outlined above, inclusive of pass-through entities, subrecipients, contractors, or collaborators. Each entity must have its own policies in place that meet these requirements or mandate that the PIs/PDs working for such entities follow those of the Recipient.

Procurement:

The Recipient must also maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts in accordance with 45 CFR §75.327 General procurement standards. No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the non-Federal entity may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the non-Federal entity.

If the non-Federal entity has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the non-Federal entity must also maintain written standards of conduct covering organizational conflicts of interest.

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Cost Category	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	Budget Period 6	Budget Period 7	Budget Period 8	Budget Period 9	Budget Period 10	Total
A. Personnel	\$ 55,514	\$ 38,305	\$ 39,454	\$ 40,638	\$ 41,857	\$ 43,113	\$ 44,406	\$ 45,738	\$ 47,110	\$ 48,524	\$ 444,658.91
B. Fringe Benefits	\$ 41,311	\$ 27,906	\$ 28,230	\$ 28,564	\$ 28,908	\$ 29,262	\$ 29,627	\$ 30,003	\$ 30,390	\$ 30,789	\$ 304,992.79
C. Travel	\$ 3,270	\$ 3,270	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 6,540.00
D. Equipment	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
E. Supplies	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 8,190	\$ 81,900.00
F. Subrecipients/ Consultants/ Contr	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 500,000.00
G. Other	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Direct Costs	\$ 158,286	\$ 127,671	\$ 125,875	\$ 127,392	\$ 128,955	\$ 130,565	\$ 132,223	\$ 133,931	\$ 135,691	\$ 137,503	\$ 1,338,091.70
J. Indirect Costs	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Project Costs	\$ 158,286	\$ 127,671	\$ 125,875	\$ 127,392	\$ 128,955	\$ 130,565	\$ 132,223	\$ 133,931	\$ 135,691	\$ 137,503	\$ 1,338,091.70

NOA Award 8/1/25-12/31/26		8/1/25-6/30/26		7/1/26-12/31/26		
Salaries	\$	48,607.00	\$	31,451.59	\$ 17,155.41	\$ -
Fring	\$	26,219.00	\$	16,965.24	\$ 9,253.76	\$ -
	\$	74,826.00	\$	48,416.82	\$ 26,409.18	\$ -
	1 Year BP 1	6 months BP 1	6 months BP2	6 months BP3		
	\$	6,015.88	\$	6,015.88	\$ 6,472.60	\$ 6,322.88
	\$	72,190.50	\$	36,095.25	\$ 38,835.63	\$ 37,937.29
	\$	2,778	\$	2,778	\$ 4,167	\$ 4,167
	\$	33,333	\$	16,667	\$ 25,000	\$ 25,000
	\$	105,523.83	\$	52,761.92	\$ 63,835.63	\$ 62,937.29
		Total	Operating	Personal Services		
SFY26	\$	105,524	\$	72,191	\$	33,333
SFY27	\$	116,598	\$	74,931	\$	41,667
SFY28	\$	126,773	\$	76,773	\$	50,000

Enter Personnel that are absolutely necessary for this specific activity. At minimum, the PUPD must be included. Identify each individual separately and provide: the title; time commitment to the project in months; time commitment to the project as a percentage of full-time equivalent; annual salary; wage rates; etc. in the below table. Explain how requested personnel funds will support the purpose and goals of this project. Describe the role, responsibilities and unique qualifications of each position.

Note: In accordance with the Consolidated Appropriations Act, no cooperative agreement funds may be used to pay an individual working on a NHS funded project at a rate that exceeds the Federal Executive Level II Pay Scale. The Federal Executive Pay scale is updated in January of each calendar year. The rates are set by Congress as part of the annual federal budget appropriations process. The "direct salary and institutional base salary" are limited to the Executive Level II of the Federal Executive Pay scale. The salary limitation applies to grants/cooperative agreements/contracts including subawards/subcontracts. <https://www.gpo.gov/policies/data-consolidating-budget-authorities.aspx>.

Please note that an individual's base salary is NOT constrained by the legislative salary cap provision. Rather, the salary cap simply limits the amount that may be awarded and charged to CMS grants and cooperative agreements. An institution may pay an individual's salary amount in excess of the salary cap with non-federal funds. Non-federal entities must disclose the % effort contributed by each individual supported by the grant. This % effort must be multiplied by the current base salary for each individual (or the salary cap amount if the base salary exceeds allowable salary cap amount) to determine the amount to be charged to the grant award.

[illegible]

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B. Fringe Benefits	\$ 41,311.28
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Itemize the fringe benefits and the respective percentages of each benefit that adds up to the % rate. If fringe benefits are covered by a federally approved rate agreement, please provide the current rate agreement included in your Negotiated Indirect Cost Rate Agreement (NICRA).

Apply the appropriate fringe benefit rate to each salary amount determined in the personnel section. Fringe benefits may include contributions for social security, employee insurance, pension plans, etc. Only those benefits not included in an organization's indirect cost pool may be shown as direct costs. List all components of fringe benefit rate. Enter a description of the Fringe funds requested, how the rate was determined, and how their use will support the purpose and goals of this proposal.

Please submit a detailed budget narrative justification for EACH line item, in paragraph format, for each cost category table.

* Add rows as necessary to reflect proposed budget.

Benefit/Component	Benefit Rate	Salaries/ Wages	Budget Period 1 Cost	Budget Period 2 Cost	Budget Period 3 Cost	Budget Period 4 Cost	Budget Period 5 Cost	Budget Period 6 Cost	Budget Period 7 Cost	Budget Period 8 Cost	Budget Period 9 Cost	Budget Period 10 Cost	Total Cost
Retirement	19.19%	\$ 55,514.48	\$ 10,653.23	\$ 7,350.73	\$ 7,571.25	\$ 7,798.39	\$ 8,032.34	\$ 8,273.31	\$ 8,521.51	\$ 8,777.15	\$ 9,040.47	\$ 9,311.68	\$ 85,330.04
Social Security & Medicare	7.65%	\$ 55,514.48	\$ 4,246.86	\$ 2,930.33	\$ 3,018.24	\$ 3,108.79	\$ 3,202.05	\$ 3,298.11	\$ 3,397.06	\$ 3,498.97	\$ 3,603.94	\$ 3,712.06	\$ 34,016.41
Group Life		\$ 55,514.48	\$ -										\$ -
Health Insurance & Dental	Flat Rate	\$ 55,514.48	\$ 25,650.64	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 17,100.43	\$ 179,554.51
Retiree Health Credit		\$ 55,514.48	\$ -										\$ -
Disability		\$ 55,514.48	\$ -										\$ -
Other	1.37%	\$ 55,514.48	\$ 760.55	\$ 524.78	\$ 540.52	\$ 556.74	\$ 573.44	\$ 590.64	\$ 608.36	\$ 626.61	\$ 645.41	\$ 664.77	\$ 6,091.83
		\$ 55,514.48	\$ -										\$ -
Fringe Totals			\$ 41,311.28	\$ 27,906.27	\$ 28,230.44	\$ 28,564.34	\$ 28,908.26	\$ 29,262.49	\$ 29,627.36	\$ 30,003.16	\$ 30,390.25	\$ 30,788.94	\$ 304,992.79

45 CFR 75.473-75.474 Travel Costs.

Please provide a clear picture of each travel event to be undertaken, by whom, provide beginning and destination of the travel; the total number of key staff who will be traveling; the total cost per trip for each individual. List separately all costs: airfare, lodging, meals (per diem), mileage (if privately owned vehicles will be used, etc.). Show all calculations. How does this travel relate to furthering the objectives of the project? Each travel occurrence for a conference requires prior approval from CMS.

Apply the appropriate reimbursement rate for mileage. please note the lowest available commercial fares for coach or equivalent accommodations must be used. Current IRS allowed rate is available at: <https://www.gsa.gov/travel/plan-a-trip/transportation/airfare-rates-pov-rates-etc/private-owned-vehicle-pov-mileage-reimbursement> If state or local policy is being used, be prepared to provide policies as justification. Costs for per diem/lodging cannot exceed the GSA approved rate; refer to (<https://www.gsa.gov/travel/plan-book/per-diem-rates>) for more specific details. If the specific travel location is not available in the GSA information, use the county or state rates assigned. Note: Per diem/meals for the first and last day of travel can only be charged at 75%.

Costs requested in the travel category should be for staff travel only. Travel for other participants, advisory committees, clinicians, etc. should be itemized on tab **G. Other**. Conference registration fees are recorded on tab **G. Other**.

Please submit a detailed budget narrative justification for EACH line item, in paragraph format, for each cost category table.

Please submit a detailed budget narrative justification for EACH line item, in paragraph format, for each cost category table.

[illegible]

[illegible]

Subrecipient means a non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other federal awards directly from a Federal awarding agency. See **45 CFR Part 75.351 Subrecipient and Contractor determinations** and **45 CFR 75.352 Requirements for pass-through entities**.

[illegible]

A consultant is an individual who gives professional advice or provides services (e.g. training, expert consultant, etc.) for a fee and who is not an employee of the grantee organization.

[illegible]

A contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the contractor. See §75.2 Contract. Characteristics indicative of a procurement relationship between the non-Federal entity and a contractor are when the contractor:

- (1) Provides the goods and services within normal business operations;
- (2) Provides similar goods or services to many different purchasers;
- (3) Normally operates in a competitive environment;
- (4) Provides goods or services that are ancillary to the operation of the Federal program; and
- (5) Is not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.

[illegible]