

Federal Resources and Efforts to Advance Sickle Cell Disease Comprehensive Systems of Care

June 18, 2026 | 2:00 PM to 3:30 PM ET

OMH
U.S. Department of Health and Human Services
Office of Minority Health

Welcome

CAPT Gayathri Kumar, MD

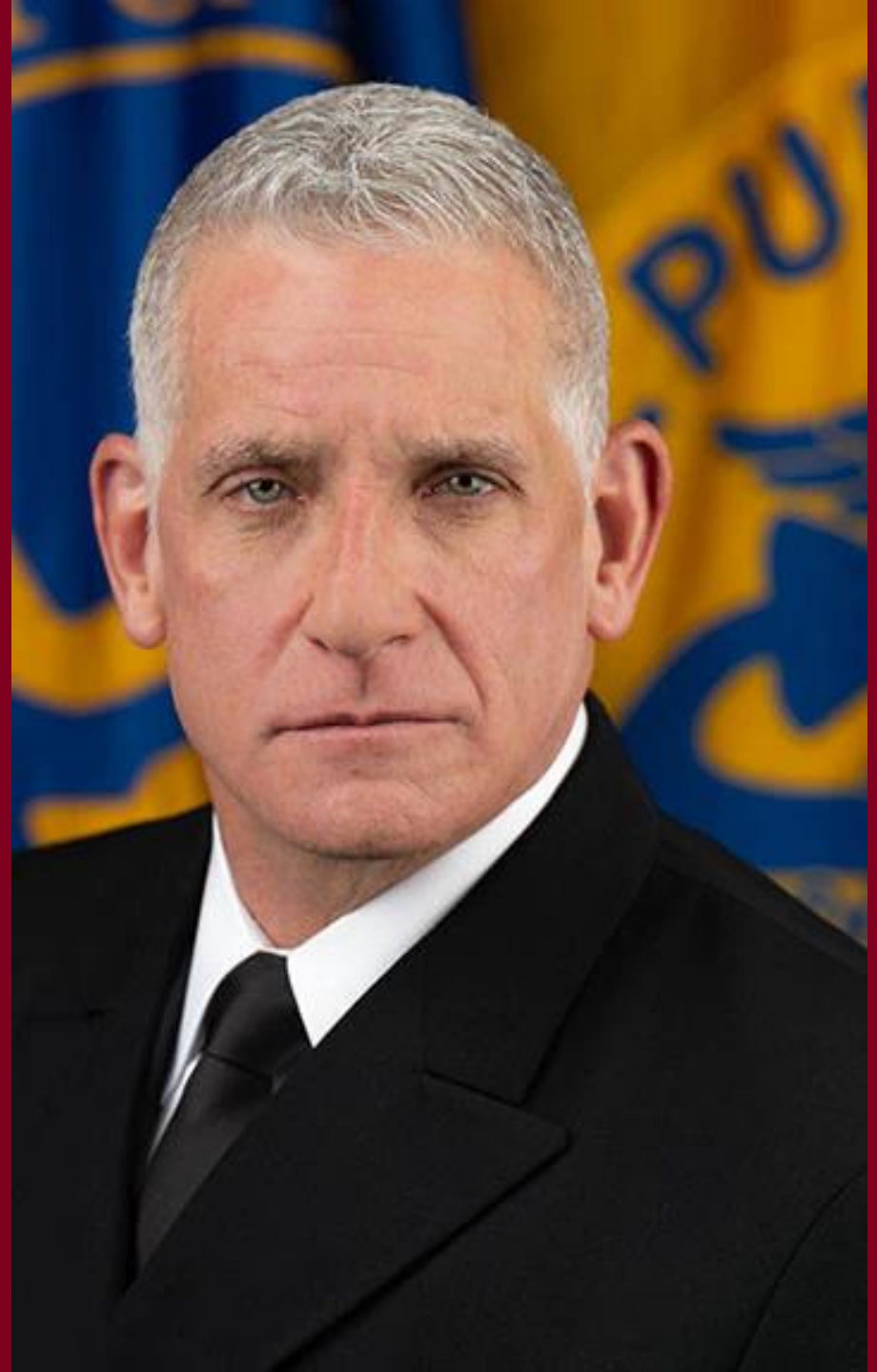
United States Public Health Service Commissioned Corps

Chief Medical Officer, Office of Minority Health

U.S. Department of Health & Human Services Office of Minority Health

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WORLD SICKLE CELL DAY



Opening Remarks

Admiral Brian Christine

Assistant Secretary for Health (ASH)

Head, United States Public Health Service Commissioned Corps

U.S. Department of Health & Human Services

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Run-of-Show and Housekeeping

CAPT Gayathri Kumar, MD

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WORLD SICKLE CELL DAY

Agenda (1 of 3)

Segment	Speaker
Welcome	**CAPT Gayathri Kumar, MD** Chief Medical Officer, Office of Minority Health U.S. Department of Health & Human Services
Opening Remarks	**ADM Brian Christine, MD** Assistant Secretary for Health (ASH) Head, United States Public Health Service Commissioned Corps U.S. Department of Health & Human Services
Talk #1: NIH Research and Programs Supporting Comprehensive Systems of Care for Sickle Cell Disease	**Griffin P. Rodgers, MD, MBA, MACP, FRCP (London)** Director, National Institute of Diabetes and Digestive and Kidney Diseases Chief, Molecular and Clinical Hematology Branch, National Heart, Lung, and Blood Institute

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Agenda (2 of 3)

Segment	Speaker
Talk #2: Health Resources & Services Administration Sickle Cell Disease Programs	**Mandy S. David, MPH, PA-C** Team Lead & Sr. Public Health Analyst of Sickle Cell Programs Health Resources & Servies Administration
Talk #3: Cell and Gene Therapy Access Model	**Abigale Sanft, MA** Director, Division of Drug Innovation Center for Medicare & Medicaid Innovation Centers for Medicare & Medicaid Services
Talk #4: Advancing Sickle Cell Disease Data Exchange: The USCDI+ SCD Minimum Core Dataset	**LaVerne Perlie, MSN, BSN, RN** Nurse Consultant Office of Programs and Implementation Office of the National Coordinator for Health Information Technology

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Agenda (3 of 3)

Segment	Speaker
Questions & Answers	**CDR Yvonne M. Santiago** Senior Advisor, OMH U.S. Department of Health & Human Services
Closing Remarks	**CAPT Mahyar Mofidi** Deputy Assistant Secretary for Minority Health Director, Office of Minority Health U.S. Department of Health & Human Services

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Housekeeping

- Chat is disabled for this event.
- Please submit your questions and comments using the Q&A box.
- Slides will be shared with all attendees following the meeting.
- This event is being recorded and will be archived on the SCD playlist on the HHS YouTube site.
- Please provide feedback by scanning the QR code or e-mailing us at: minorityhealthinfo@hhs.gov.

Email Us

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NIH Research and Programs Supporting Comprehensive Systems of Care for Sickle Cell Disease

Griffin P. Rodgers, MD, MBA, MACP, FRCP (London)

Director, National Institute of Diabetes and Digestive and Kidney Diseases

Chief, Molecular and Clinical Hematology Branch, National Heart, Lung, and Blood Institute

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WORLD SICKLE CELL DAY

HHS OFFICE OF MINORITY HEALTH · NATIONAL WEBINAR SERIES (PART 2)

NIH Research and Programs Supporting Comprehensive Systems of Care for Sickle Cell Disease

Griffin P. Rodgers, M.D., M.B.A., M.A.C.P., F.R.C.P. (London)
Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Chief, Molecular and Clinical Hematology Branch, NHLBI

June 18, 2026

A treatable disease — when patients can reach the right care

~100,000

Americans live with SCD;
>20 million people worldwide

>95%

of children now survive into adulthood — a triumph of care

2nd decade

of life is when morbidity and mortality begin to rise sharply

The care gap we must close

Life expectancy has more than doubled since 1972 — yet gains in longevity and quality of life lag behind, because many adults lose access to knowledgeable, coordinated care.

Too few providers are trained in SCD; services are fragmented; and patients face well-documented disparities in access. A comprehensive system of care exists to bridge that gap across the lifespan.

FRAMEWORK

NIH reinforces every link of comprehensive care

Evidence base & therapies

Discovery research that produced today's disease-modifying drugs, transplant, and cures

Clinical practice guidelines

National, evidence-based standards that let any clinician deliver appropriate SCD care

Implementation science & registries

Identifying and removing the real-world barriers to high-quality care

Data infrastructure & standards

Common data elements and repositories that make care measurable and reusable

Workforce & community engagement

Patient-centered research and training that build trust and capacity

Access, equity & global reach

Making affordable, effective care reach every patient — at home and abroad

EVIDENCE BASE & THERAPIES

Research delivered the modern SCD treatment toolkit

Hydroxyurea — first FDA-approved disease-modifying therapy

NIH-led Multicenter Study of Hydroxyurea: ~50% fewer pain crises, fewer transfusions and acute chest episodes

Transfusion & chronic disease management

Stroke prevention, iron-overload monitoring, and supportive care anchored in NIH-supported evidence

Hematopoietic stem cell transplant

NIH nonmyeloablative adult protocol: ~90% overall survival with durable disease-free survival and no GVHD

Two FDA-approved gene therapies (December 2023)

First cell-based gene therapies approved for a genetic disease — built on decades of NIH discovery science

Translating evidence into everyday practice



NHLBI Evidence-Based Management of SCD

Expert Panel Report (2014) — the standard national reference

- Built for primary care and emergency clinicians — most providers see few SCD patients
- Covers health maintenance: immunizations, and screening for renal, pulmonary, and stroke risk
- Management of acute and chronic complications across the lifespan
- Indications and monitoring for hydroxyurea and transfusion
- Complemented by ASH evidence-based guidelines (2014–2021)

But guidelines alone aren't enough

~1 in 3

providers were unaware of the 2014 guidelines

Only 22%

felt their patients' mental-health needs were being met

→ *closing this gap requires implementation science*

SCDIC: fixing how care is actually delivered

Sickle Cell Disease Implementation Consortium — NHLBI-funded, established 2016

8

clinical centers using implementation science

~2,400

adolescents & adults (15–45) in a national registry

Pediatric→Adult

transition in care is a central target

What it does

- Community-based needs assessment of patients and providers
- Builds and maintains a longitudinal SCD patient registry
- Implementation studies on transition, hydroxyurea uptake, ED care, and staying linked to a specialist

What it found

- Top patient-reported barriers: prior negative experiences with the healthcare system, and cost
- “Unaffiliated” patients — no specialist visit in 2 years — carry heavier social-determinant burdens
- Mental-health support is a major unmet need across sites

DATA INFRASTRUCTURE & STANDARDS

Standardized data make care measurable — and improvable

Common Data Elements

CureSCi consensus variables (finalized 2021), validated instruments (PROMIS, NIH Toolbox), and template case-report forms for SCD studies

Metadata Catalog

A searchable, open catalog that harmonizes data across 30+ NIH-funded SCD studies for reuse and pooled analysis

Repositories & biobank

NHLBI BioLINCC and BioData Catalyst share data and biospecimens; a dedicated SCD stem-cell bank supports curative research

Why it matters for care: standardization → interoperability → stronger cross-study evidence → better, more consistent care decisions for every patient.

Cure Sickle Cell Initiative (CureSCi)

NHLBI-led, patient-focused effort to accelerate safe, effective, widely adoptable gene-based cures

From first-in-human to phase 2

Phase 1 — first 10 participants
Gene therapy shown safe and effective at reducing pain crises

Phase 2 — launched 2024
Same therapy advanced to a larger trial on the strength of those results

Preliminary results from the broader CureSCi portfolio are expected within several years.

Designed around patients

- People living with SCD engaged at every level of the Initiative
- Links academia, industry, clinicians, and the community
- Continuously scouts and moves new gene-editing approaches into trials

ACCESS & GLOBAL REACH

Comprehensive care means access for every patient

An access imperative: SCD disproportionately affects Black Americans and people of African descent. Closing care gaps is inseparable from advancing health access.

$100M + $100M

NIH–Gates Foundation collaboration to develop affordable, gene-based cures deliverable in low-resource settings

~75%

of the world's SCD births occur in sub-Saharan Africa — where NIH is building research infrastructure and point-of-care newborn screening

Goal: cures and quality care that reach all patients — not only those in high-income settings.

PUTTING IT TOGETHER

NIH support across the comprehensive-care continuum



Newborn screening

Early identification across the lifespan

Primary + specialty care

Guidelines standardize practice

Registry & data

Measure barriers and outcomes

Trials & cures

CureSCi advances the pipeline

Global scale

Affordable, equitable access

NIH research and programs reinforce every link — from a child's first screen to a globally accessible cure.

KEY TAKEAWAYS

1

Research delivers the therapies

From hydroxyurea to transplant to two FDA-approved gene therapies

2

Programs make care deliverable

Guidelines, implementation science, registries, and data close the care gap

3

Cures + access extend care to all

CureSCi and the global/equity agenda reach every patient

Resources

nhlbi.nih.gov/research/sickle-cell-disease
curesickle.org
niddk.nih.gov

Thank you.

With thanks to our partners

HHS Office of Minority Health
HRSA · CMMI · ONC
— and the SCD patient community



Health Resources & Services Administration Sickle Cell Disease Programs

Mandy S. David, MPH, PA-C

Team Lead & Sr. Public Health Analyst of Sickle Cell Programs

Health Resources & Servies Administration

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HRSA
Health Resources & Services Administration

Health Resources and Services Administration Sickle Cell Disease Programs

June 18, 2026

Mandy S. David, MPH, PA-C
Team Lead & Senior Public Health Analyst of Sickle Cell Disease Programs
Maternal and Child Health Bureau (MCHB)
Division of Services for Children and Youth with Special Health Needs

Vision: Healthy Communities, Healthy People





Overview

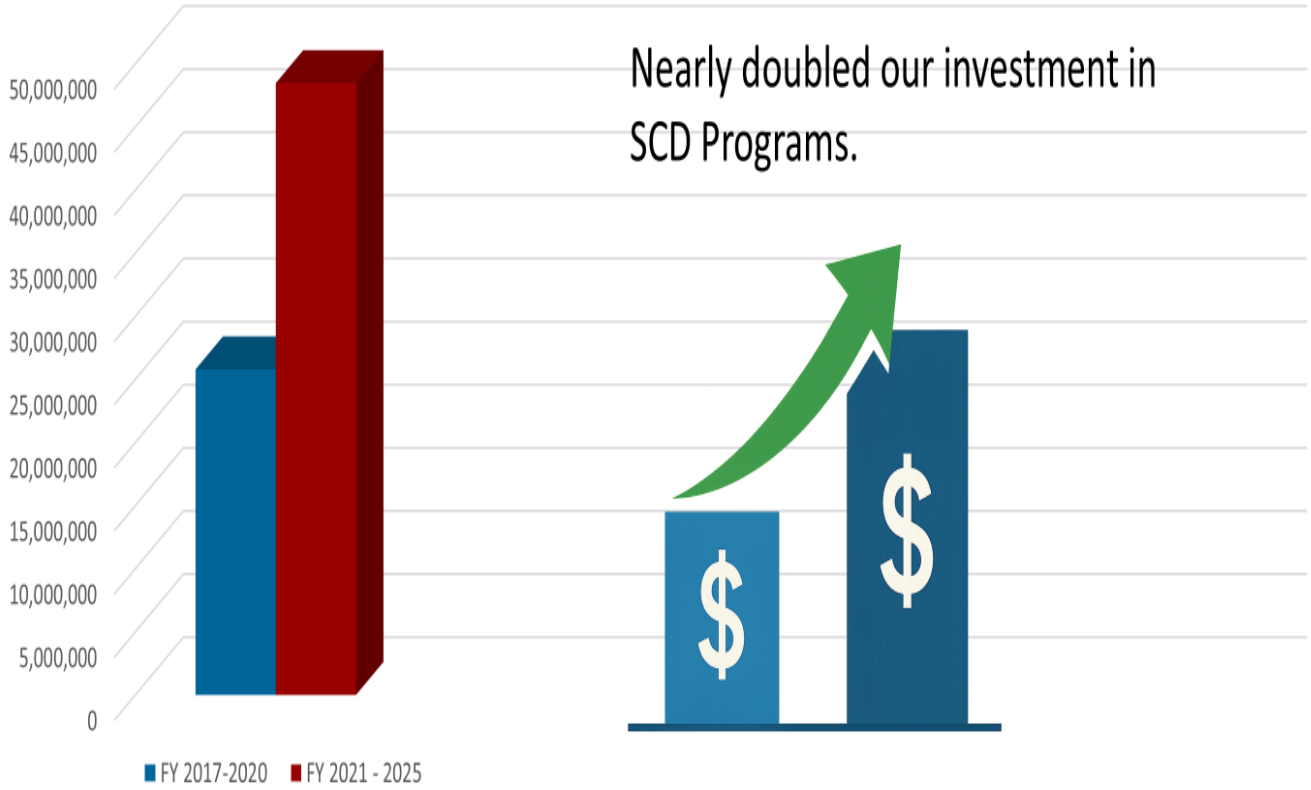
- History of HRSA & SCD
- Overview of HRSA SCD Programs
- Sickle Cell Disease (SCD) and the System of Comprehensive Care

Challenges Impacting the System of Care for SCD Patients and their Families

- Barriers to accessing comprehensive care, new therapies, education, and coordinated support
- After newborn screening, individuals with SCD can be lost to follow-up
- Access to care (distance to SCD specialists, few SCD specialists)
- Emergency department care utilization
- Transition from the pediatric to adult health care system
- Community and economic factors negatively impact the health of individuals living with SCD
- Social drivers affect quality of life for individuals with SCD

History of HRSA Support for Sickle Cell Disease Activities

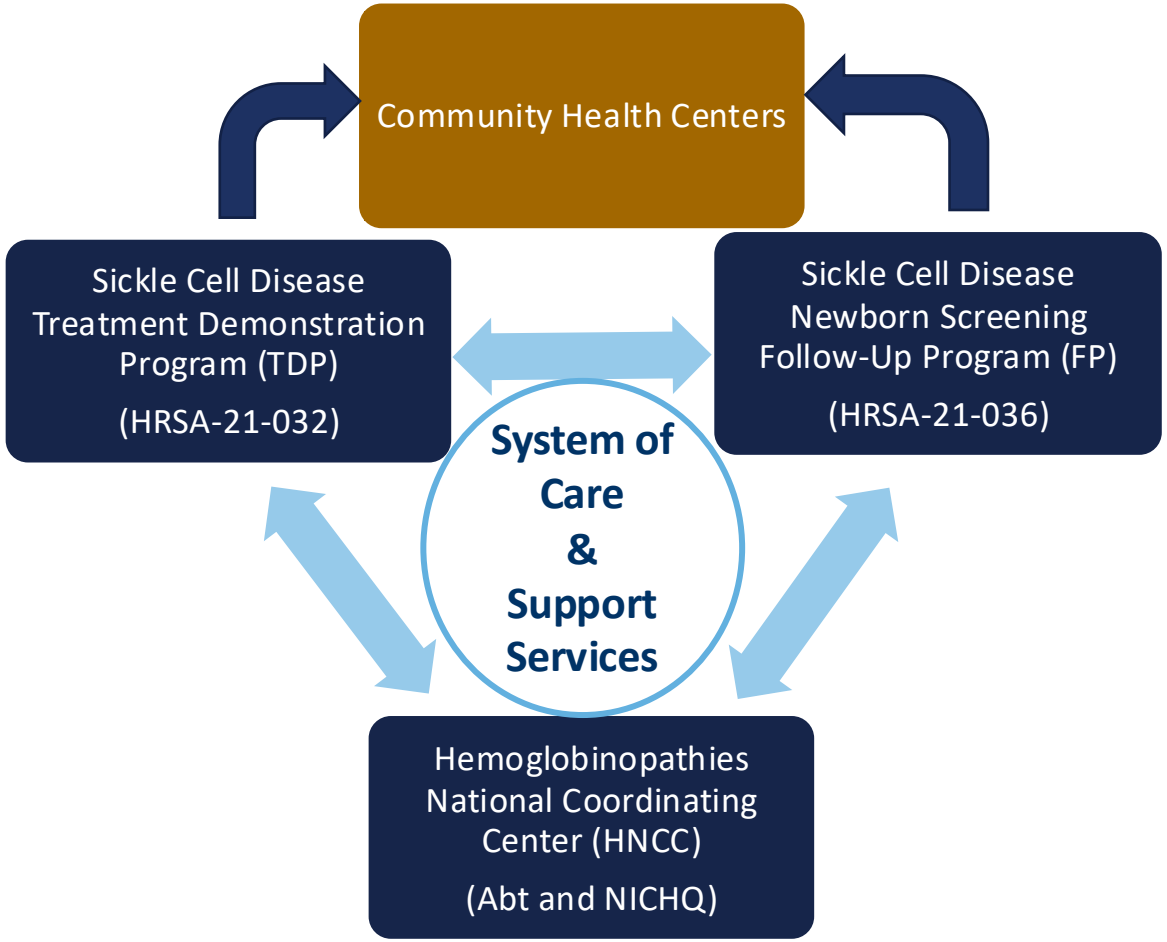
- ✓ HRSA has supported SCD activities since the 1970s.
- ✓ HRSA's investment in SCD activities has nearly doubled when comparing the current cycle with the previous cycle.
- ✓ Currently, the SCD Programs are in the 5th cycle of the regional SCD treatment demonstration program



HRSA Sickle Cell Disease Programs

Program Name	Total Number of Grantees	Project Period	Start Date	Funding Stream
Sickle Cell Disease Treatment Demonstration Program (TDP)	5 Regional Grantees	5 years	9/1/21	Cooperative agreement 42 USC § 300b-5(b) (§1106(b) of the Public Health Service Act
Sickle Cell Disease Newborn Screening Follow-up Program (FP)	25 Community-Based Organizations	5 years	9/1/21 (+5 starting 8/22 for 4 years)	Grant Special Projects of Regional and National Significance (SPRANS)
Hemoglobinopathies National Coordinating Center (HNCC)	1 Awardee	5 years	9/1/21	Contract 42 USC § 300b-5(b) (§1106(b) of the Public Health Service Act

HRSA Sickle Cell Disease Programs: Bridging Communities and Clinicians

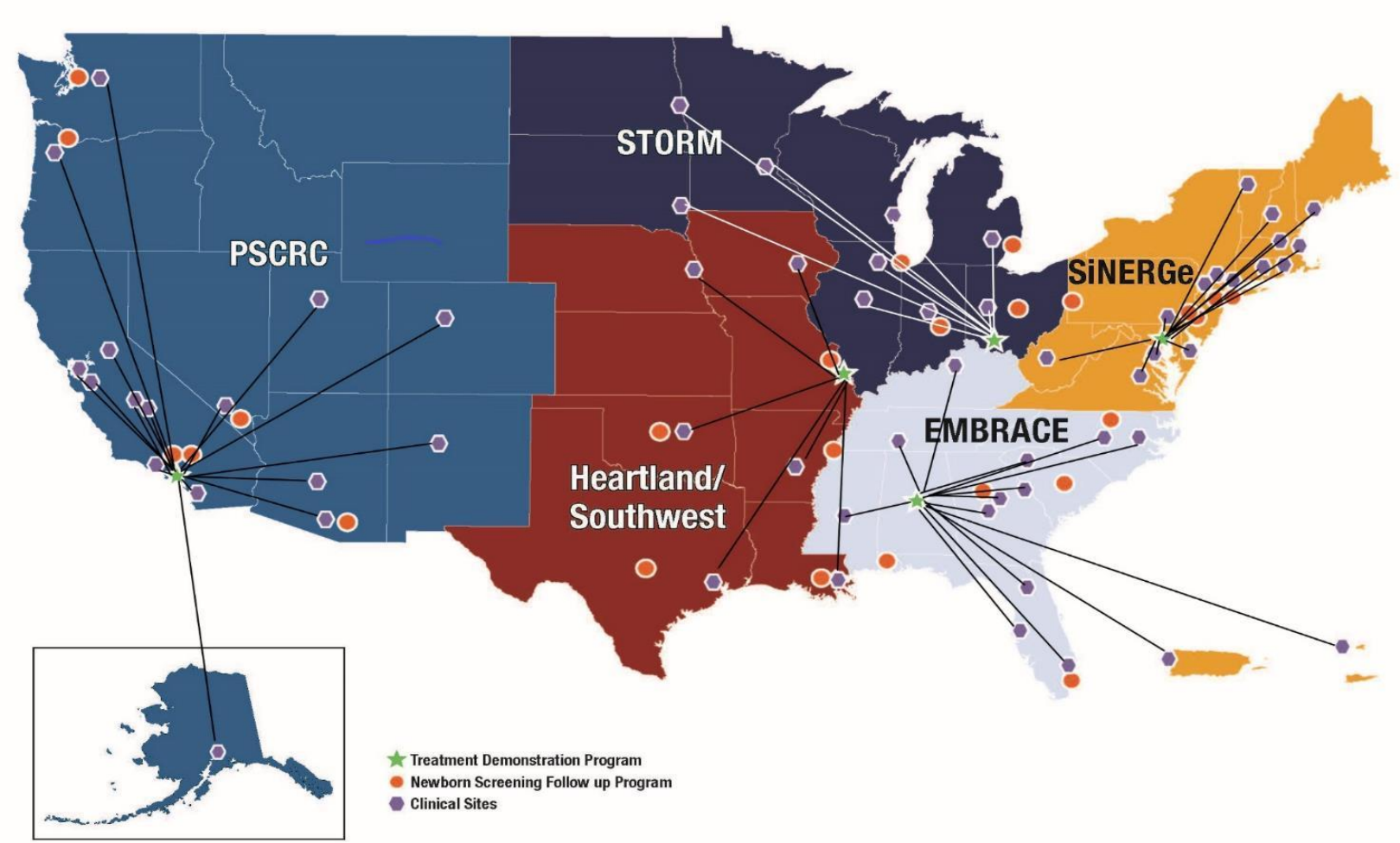


Strengthen the **system of care** and **support services:**

- Educating patients, families, and clinicians
- Linking individuals and families to evidence-based care
- Strengthening partnerships between clinicians, community organizations, and other stakeholders

HRSA Sickle Cell Disease Programs

We support clinics and community organizations that help with testing, counseling, treatment, and education.



HRSA Sickle Cell Disease Program Awardees

	Northeast	Midwest	Pacific	Heartland/Southwest	Southeast
Treatment Demonstration Programs (TDPs)	The Johns Hopkins University (MD)	Cincinnati Children's Hospital Medical Center (OH)	The Center for Comprehensive Care and Diagnosis of Inherited Blood Disorders (CA)	The Washington University (MO)	University of Alabama at Birmingham (AL)
Newborn Screening Follow-up Programs (NBS FPs)	Sickle Cell Disease Association of America – Philadelphia-Delaware Valley Chapter (PA)	Sickle Cell Disease Association of Illinois (IL)	Cayenne Wellness Center and Children's Foundation, Inc. (CA)	Sickle Cell Association (MO)	Piedmont Health Services and Sickle Cell Agency (NC)
	Children's Sickle Cell Foundation, Inc. (PA)	Sickle Cell Disease Association of America – Michigan Chapter (MI)	Hemostasis and Thrombosis Center of Nevada (NV)	Baton Rouge Sickle Cell Anemia Foundation, Inc. (LA)	University of Miami (FL)
	The Sickle Cell Association of New Jersey, Inc. (NJ)	Ohio Sickle Cell and Health Association, Inc. (OH)	Sickle Cell Anemia Foundation of Oregon, Inc. (OR)	Sickle Cell Texas Marc Thomas Foundation (TX)	Sickle Cell Foundation of Georgia, Inc. (GA)
	Sickle Cell/Thalassemia Patients Networks, Inc. (NY)	Martin Center, Inc. (IN)	Sickle Cell Foundation of Arizona, Inc. (AZ)	Supporters of Families with Sickle Cell Disease, Inc. (OK)	James R. Clark Memorial Sickle Cell Foundation (SC)
	Crescent Foundation, Inc. (NJ)		Metropolitan Seattle Sickle Cell Task Force (WA)		Sickle Cell Disease Association of America – Mobile Chapter, Inc. (AL)
			Sickle Cell Disease Foundation (CA)		Sickle Cell Foundation of Tennessee (TN)

Sickle Cell Disease Program Activities

- Implemented community health worker SCD training
- Completed quality improvement projects
- Partnership and collaboration with/among SCD grantees
- Conducted Project ECHO sessions (telementoring)
- Educated and trained providers (including advanced practice providers)
- Developed materials College Readiness Guide, Transition Guide
- Completed SCD All-Awardee annual meetings
- Awarded supplemental awards for additional SCD transitional work
- Established Education & Training Workgroup
- Collaborated with Federal Interagency Workgroup (HHS, CDC, NIH, FDA, CMS, and other)
- Established Data Collection Advisory Board

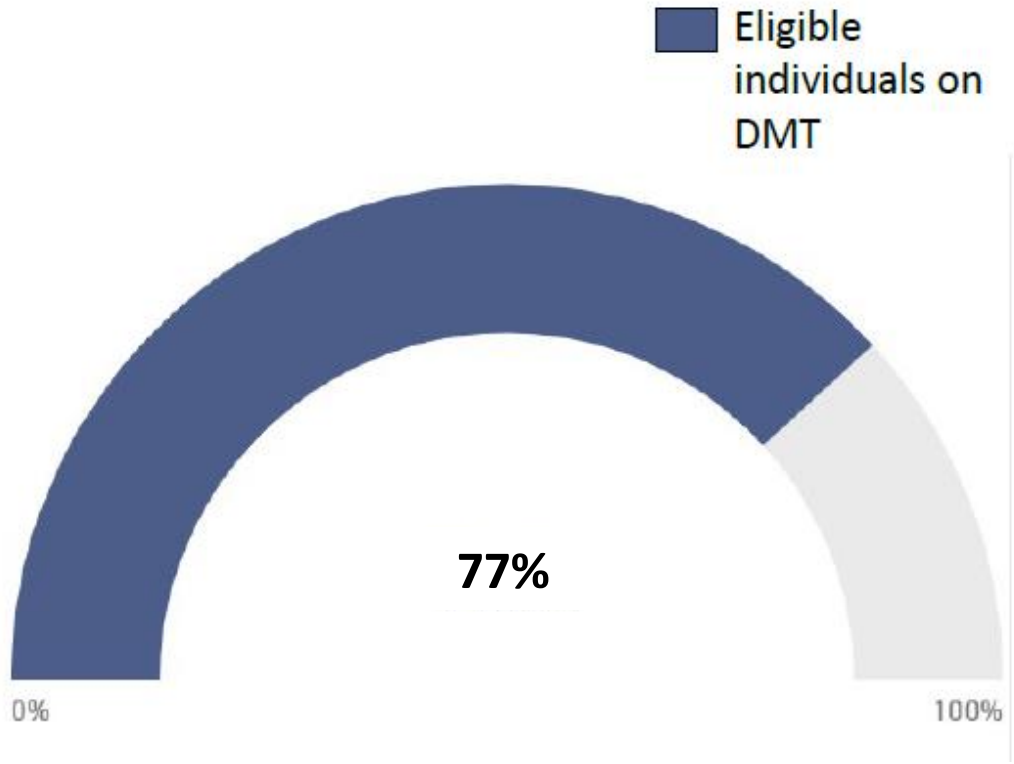
FY 25 SCD Program Data: Individuals with SCD Served

Program Name	Numbers served
Sickle Cell Disease Treatment Demonstration Program (TDP)	**25, 807 served** 63% Children, adolescents, and young adults (age 1-25) Adult men and women and post partum women
Sickle Cell Disease Newborn Screening Follow-up Program (FP)	**12, 348 served** 49% Children, adolescents, and young adults (age 1-25) Adult men and women

SOURCE: Discretionary Grants Information System (DGIS) Non-Competing Continuation Performance Report. Report period 9/1/2024-8/31/2025.

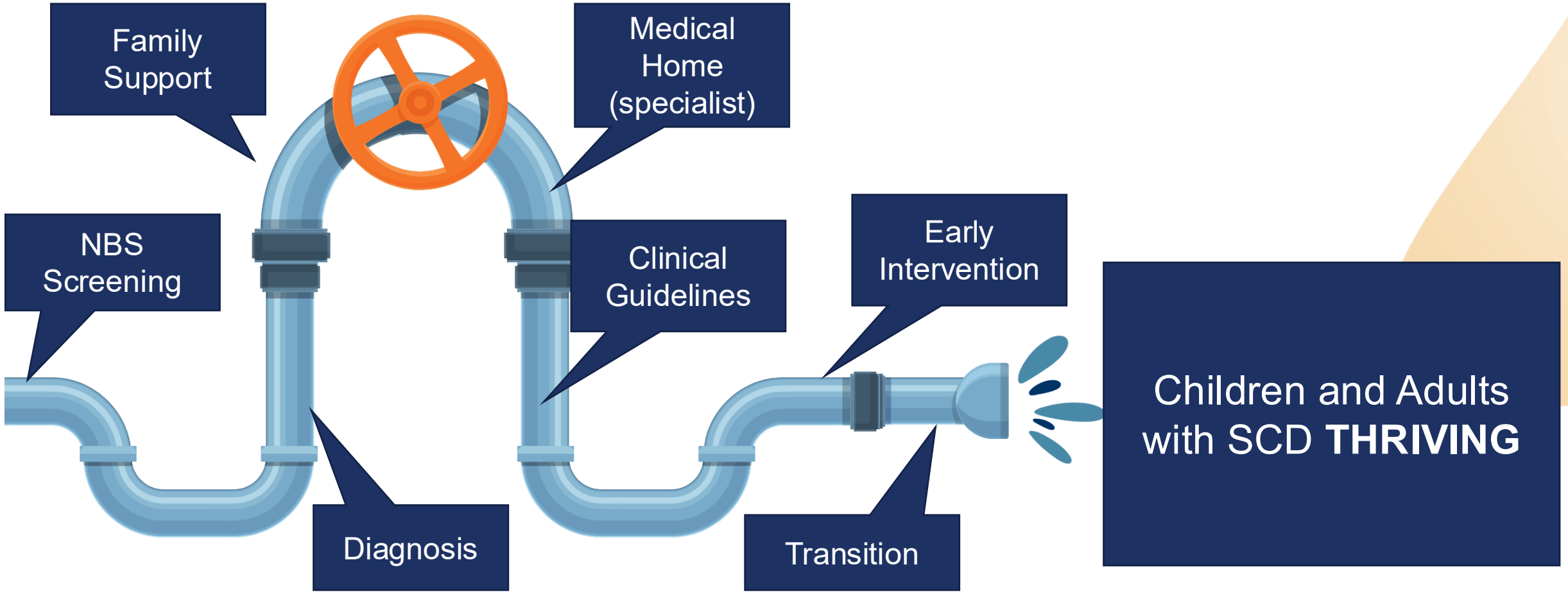
FY 25 SCD Program Data: SCD TDP: % Individuals on Disease-Modifying Therapies

77% of eligible individuals served were on disease-modifying therapies



SOURCE: Discretionary Grants Information System (DGIS) Non-Competing Continuation Performance Report. Report period 9/1/2024-8/31/2025.

SCD System of Care & Support Services



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Cell and Gene Therapy Access Model

Abigale Sanft, MA

Director, Division of Drug Innovation

Center for Medicare & Medicaid Innovation

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Cell and Gene Therapy (CGT) Access Model

Center for Medicare and Medicaid Innovation
June 2026

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Model Framework

The CGT Access Model aims to bring states together to negotiate collectively with manufacturers, supported by CMS.

The Cell and Gene Therapy (CGT) Access Model is a framework wherein CMS negotiates with manufacturers on behalf of states for outcomes-based agreements (OBAs) for CGTs that cover Medicaid enrollees.



CMS directly negotiates Key Terms of OBAs with manufacturers



States decide whether to enter into agreements with manufacturers regarding OBA Key Terms



CMS supports implementation, reconciliation, and evaluation

Model Structure

The CGT Access Model seeks to test whether a CMS-led approach to negotiating and administering Outcomes-Based Agreements (OBAs) for CGTs will improve access and health outcomes for people with Medicaid coverage and reduce health care costs. This test includes a comprehensive strategy for addressing a range of barriers to equitable access to CGTs.

Role of CMS

CMMI will negotiate key terms for agreements between states and manufacturers, including CGT market access and rebate payments.

Participant Eligibility

All States and Territories that participate in the Medicaid Drug Rebate Program (MDRP) can participate in the model if they meet requirements.

Manufacturers that participate in the MDRP and market FDA-approved or -licensed gene therapies for the treatment of SCD can participate in negotiations with CMS.

CMS will negotiate discounted pricing

with manufacturers to relieve the burden on states and increase access for beneficiaries.

CMS will tie manufacturer payment to specific outcomes,

such as reduction in pain-crises.

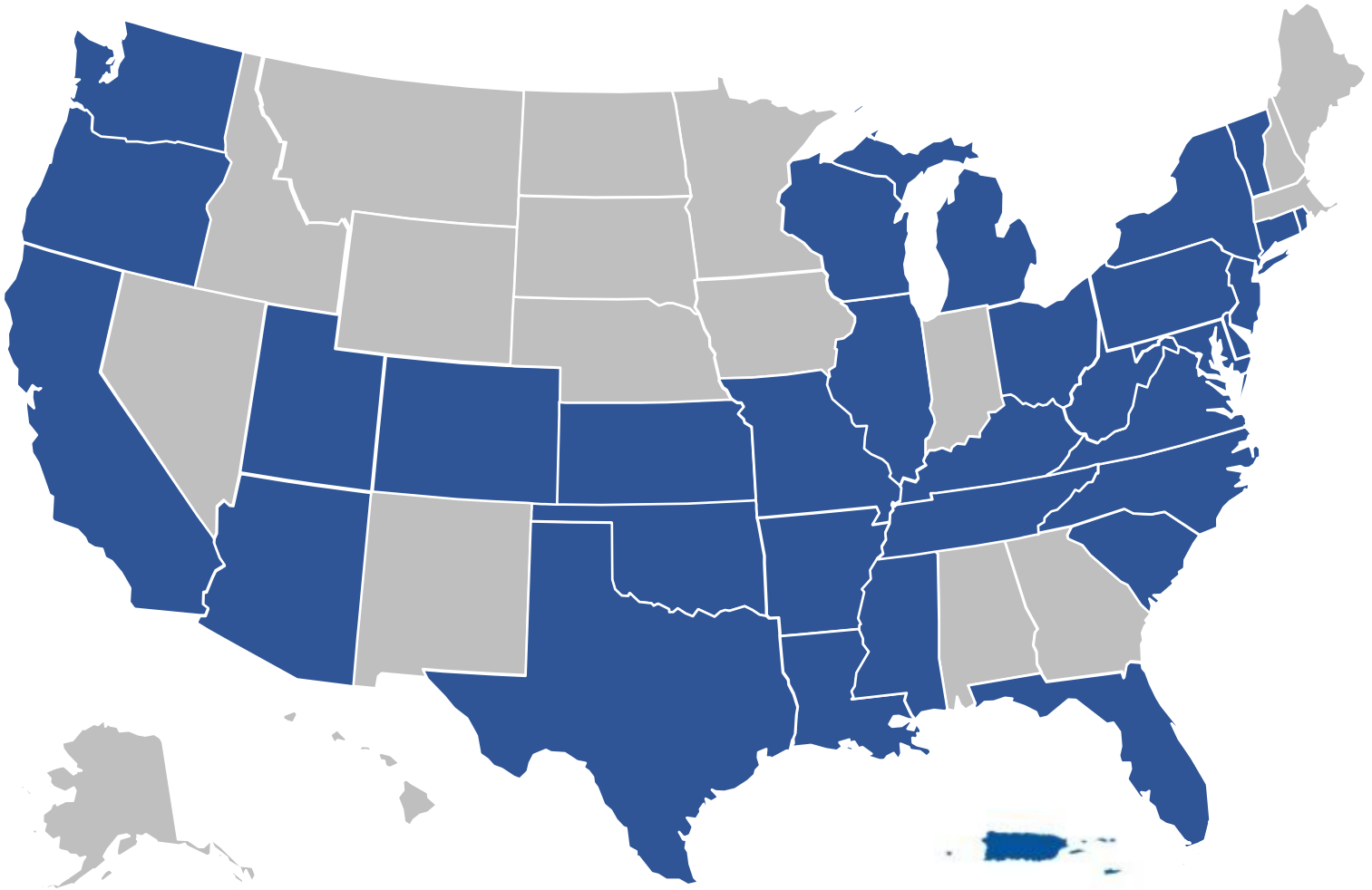
CMS will offer optional funding

to states to support implementation and activities that promote access to care.

CMS will support states to operationalize the model,

such as providing technical assistance, specifying requirements on data collection, and collecting clinical and claims outcomes.

32 States Plus D.C. and Puerto Rico are Participating in the Model

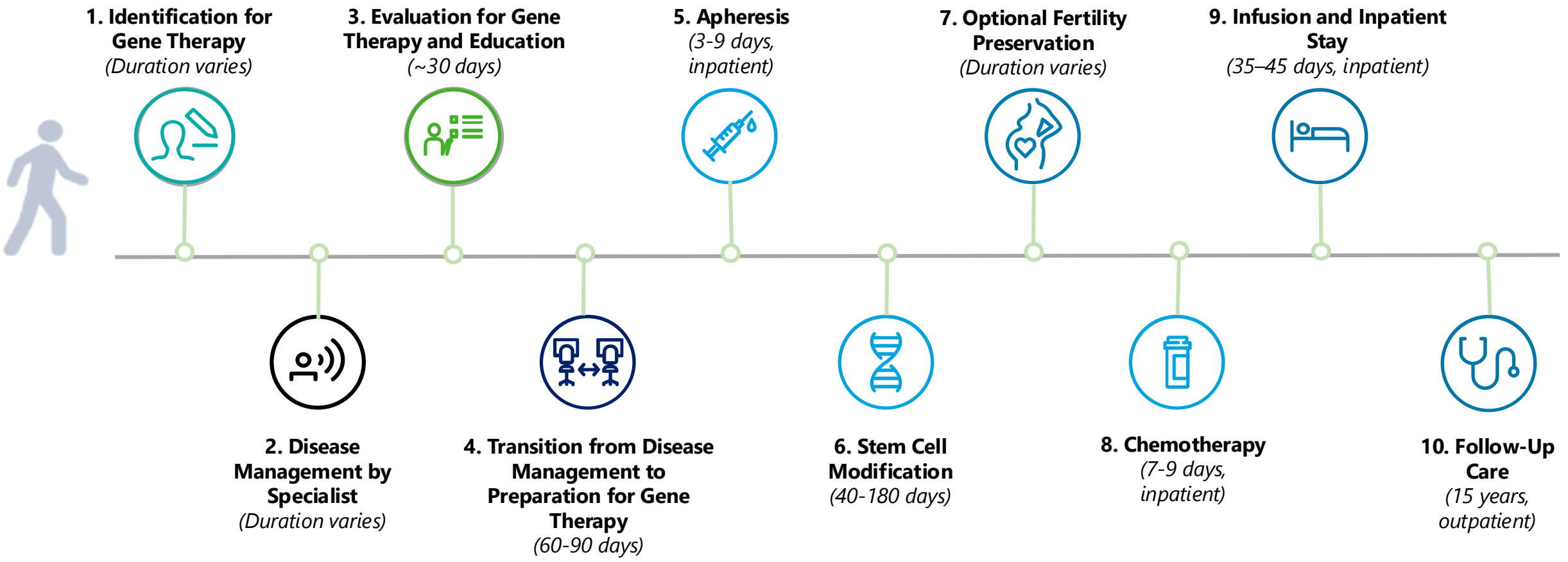


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* Participating States also receiving CGT Access Model Cooperative Agreement funding

Illustrative Patient Care Journey

The care journey for SCD gene therapy is long, rigorous, and complex.



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Potential Care Delivery Gaps

Cooperative Agreement funding is designed to help states address some of the potential care delivery gaps individuals with Medicaid coverage may experience in the SCD gene therapy care journey.

Topic	Potential Care Delivery Gaps
Patient Knowledge	• Patient awareness of gene therapy • Patient knowledge of & access to non-emergency medical transportation (NEMT)
SCD Care	• Access to SCD specialist • Access to out-of-state providers
Other Specialty Care	• Access to behavioral health providers • Access to other specialty care services and providers
Social Needs	• Services to address access barriers, including childcare
Care Coordination	• Care coordination / patient navigation • Navigating changes in insurance coverage

Key Requirements for States

States participating in the CGT Access Model must meet the following requirements:*



- Execute value-based purchasing supplemental rebate agreements (VBP SRAs) with manufacturers that reflect the Key Terms negotiated by CMS
- Establish a standardized access policy for included gene therapies
- Require providers to follow requirements for data reporting and claims submissions
- Ensure necessary transportation and related travel expenses to beneficiaries (NEMT)
- Pursue state plan amendments (SPAs) where appropriate
- Carve included gene therapies out of any inpatient payment bundle
- Ensure beneficiaries have access to care with in-state or out-of-state qualified gene therapy provider(s)
- Meet minimum T-MSIS data requirements

* As applicable, these requirements apply with respect to a state's beneficiaries enrolled in fee-for-service and Medicaid managed care. As discussed earlier, a state may choose to begin in 2025 with only their fee-for-service members and bring their managed care lives into the agreement as late as January 1, 2026.

Manufacturer Support to Address Barriers



Fertility Preservation

CMS will require manufacturers to pay for a defined scope of fertility preservation services.

- Manufacturers pay for collection, cryopreservation, and storage of reproductive materials in clinical trials
- Meets conditions of CMS-sponsored model safe harbor 42 CFR 1001.952(ii)
- May yield learning to inform state Medicaid agencies' future decision-making regarding coverage for fertility preservation services in connection with CGT



Treatment Centers

CMS intends to negotiate an access policy with manufacturers that ensures treatment centers offer appropriate, multi-disciplinary care.

- Behavioral Health Services (mental health, SUD treatment, pain management)
- Case Management

Model Timeline

Model Design

CMS incorporated insights and expertise through conversations with interested parties (states, manufacturers, beneficiary groups, clinicians).

Nov 2022-Dec 2023

Model Announcement

Information about the CGT Access Model is available via the model website, the Model Overview Webinar, and the State Webinar.

Jan 2024

Engagement with Interested Parties

States had the opportunity to meet with CMS and submit non-binding letters of intent.

CMS sought additional input from states, clinicians, and patient groups on the model.

Jan 2024- May 2024

Manufacturer Negotiation

CMS negotiated Key Terms of an outcomes-based agreement (OBA) on behalf of states.

May – Nov 2024

State Applications Open

Key Terms of the OBA were disclosed to states through the CMS MDP System.

States had the opportunity to decide whether to participate.

Dec 2024 – March 2025

States Begin Model Performance

CMS is supporting states in administering OBAs through collection of clinical and claims data, payment reconciliation, and evaluation of data, as well as technical assistance.

Jan 2025-Jan 2026

Share your ideas of future conditions or other directions for the CGT Access Model with the CGT Access Model Team at CGTModel@cms.hhs.gov using the subject line "Future Model Considerations."

THANK YOU!

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Advancing Sickle Cell Disease Data Exchange: The USCDI+ SCD Minimum Core Dataset

LaVerne Perlie, MSN, BSN, RN

Nurse Consultant

Office of Programs and Implementation

Office of the National Coordinator for Health Information Technology

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DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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ONC Office of the National Coordinator for Health Information Technology

Advancing Sickle Cell Disease Data Exchange: The USCDI+ SCD Minimum Core Dataset

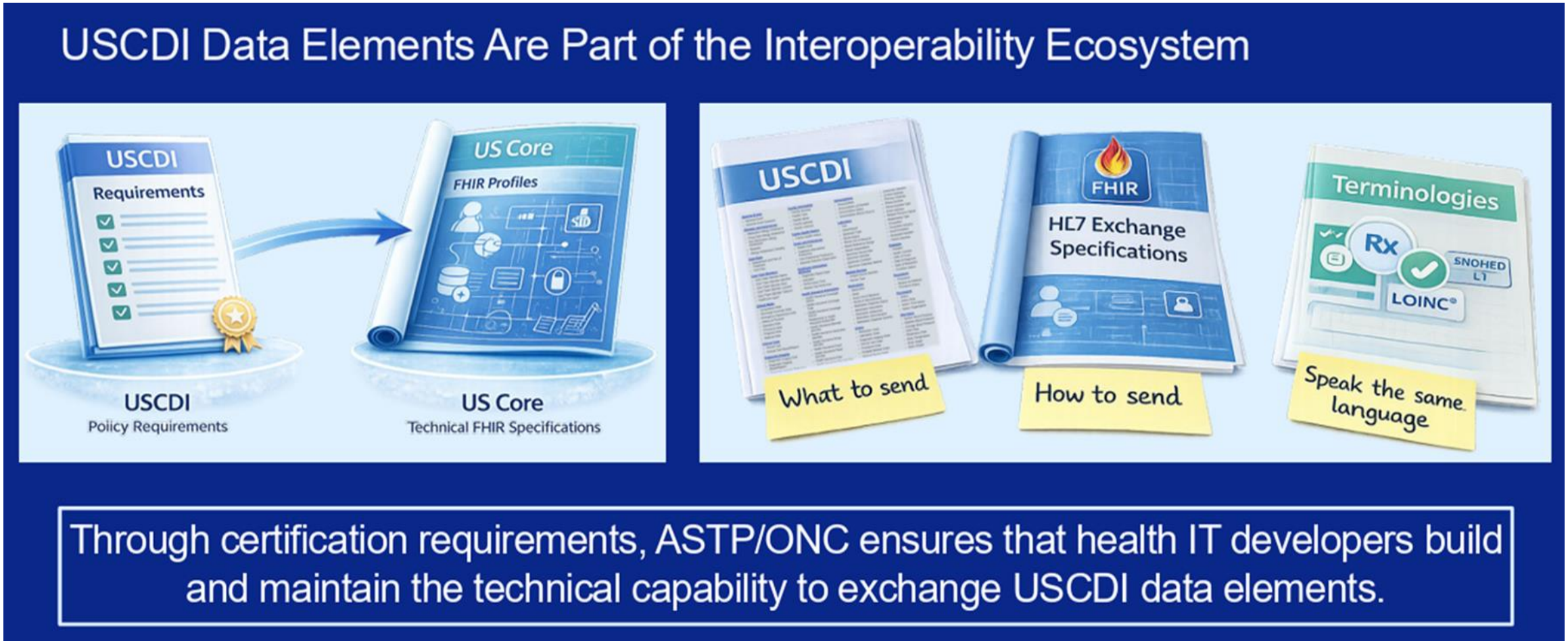
LaVerne Perlie, MSN, BSN, RN
Nurse Consultant
Alignment and Engagement Division
Office of the National Coordinator for Health Information Technology

June 18, 2026

Agenda

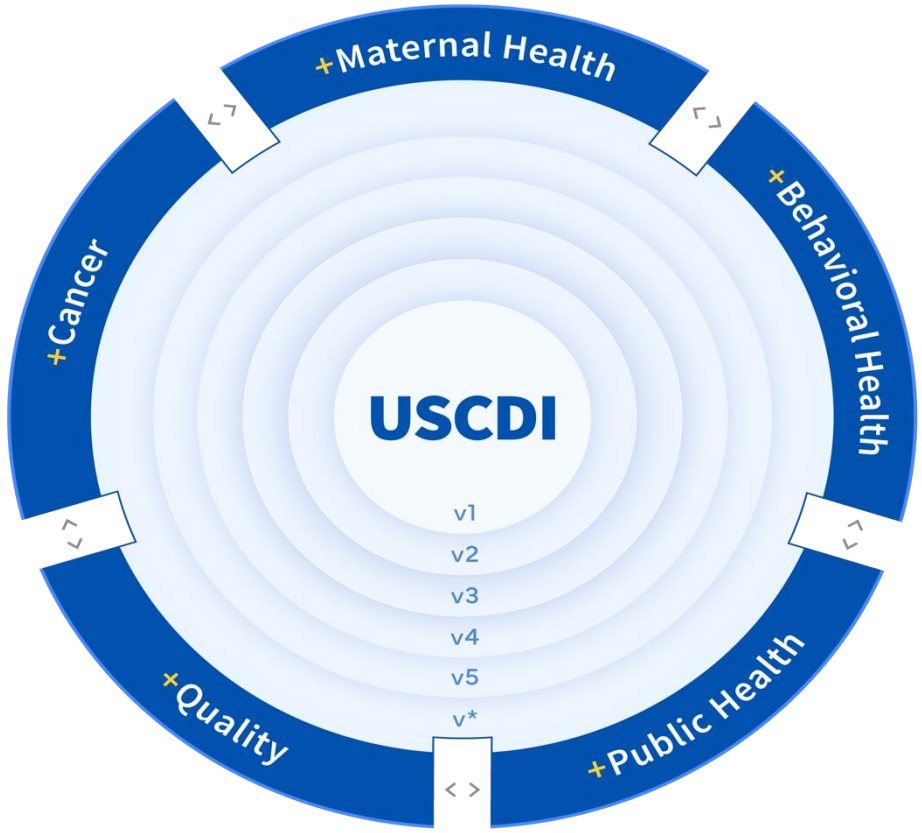
- ONC and Sickle Cell Disease Collaboration
- United States Core Data for Interoperability and USCDI+
- USCDI + SCD Minimum Core Dataset Project
- Public Comment on the Draft USCDI+SCD Data Set

United States Core Data for Interoperability



https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi

USCDI+: Extending Beyond the USCDI



https://www.healthit.gov/topic/interoperability/uscdi-plus

- Unique program and use case-specific data needs are sometimes not fully met by USCDI.
- ASTP's USCDI+ initiative helps government and industry partners build on USCDI to support specific program needs.
- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.
- Seeks to leverage programs and authorities across HHS to drive adoption.

USCDI+ Sickle Cell Disease



USCDI + Sickle Cell Disease Dataset Objectives

Identify, prioritize, and develop two high-value use cases for standardized data exchange for persons living with SCD.

Produce a list of minimum SCD data elements and their value sets necessary to satisfy the use cases.

Create, test, and pilot a FHIR Implementation Guide (IG) to exchange USCDI+ SCD data elements.

Technical Expert Panel







































SCD Data Exchange: An Analysis of the Landscape and Insights from Stakeholders on Complex Systems

- There are instances of missed or delayed identification of individuals with sickle cell disease (SCD).
- SCD data exchange is fragmented and inconsistent.
- Lack of reliable access to essential clinical information during acute events.
- Lack of standardized SCD data elements.
- Lack of a unified national approach to collecting or harmonizing longitudinal SCD data.
- Widespread agreement on the need for data standardization.

USCDI+ SCD Use Cases

Use Case A: Sickle Cell Disease Diagnosis

Use Case B: Sickle Cell Disease Emergency Care

Use Case A: Sickle Cell Disease Diagnosis

This use case is driven by two primary goals:

- First, to ensure that all individuals living with SCD have a recorded diagnosis in their patient records that includes the specific SCD subtype.
- Second, to improve the identification of individuals living with SCD by enabling accurate and consistent sharing of documented SCD diagnoses and subtypes between healthcare systems.
- Achieving these goals supports continuity of care and improved health outcomes.
- Accurate diagnosis documentation is foundational to improving care coordination, clinical decision-making, and population-level health outcomes for individuals with SCD
- Accurate subtype documentation enables clinicians to anticipate complications better, tailor treatment plans, and provide personalized, proactive care.

Use Case B: Sickle Cell Disease Emergency Care

Emergency departments frequently treat SCD patients without access to their medical history, previous treatments, or pain management plans.

This use case aims to:

- Ensure that emergency teams receive timely and accurate information to deliver safe and effective care.
- Ensure that treatments or interventions provided to individuals with Sickle Cell Disease (SCD) during acute episodes align with their previous care and are properly documented.

The SCD Emergency Care use case emphasizes:

- The clinical necessity for access to relevant past medical history, including diagnoses, problems, lab results, procedures, treatment records, and current medications, to manage SCD-related complications effectively.
- Ensuring all individuals with SCD receive high-quality care from providers who are informed by the patients' medical histories during acute episodes.

USCDI+SCD Proposed Draft Data Elements for Data Exchange

USCDI+ SCD Proposed Data Elements

Allergies and Intolerances
- Drug Class Allergy Intolerance
- Medication Allergy Intolerance
- Non-Medication Allergy Intolerance
- Reaction

Biologically Derived Products
- **Blood Transfusion Product Antibody (NEW) (B)**
- **Blood Transfusion Product Antigen (NEW) (B)**
- **Blood Transfusion Product Blood Type (NEW) (B)**
- **Blood Transfusion Product Name (NEW) (B)**

Care Plan
- Assessment and Plan of Treatment
- **Care Plan (NEW) (A)**

Care Team Members
- Care Team Member Identifier
- Care Team Member Locator
- Care Team Member Name
- Care Team Member Role
- Care Team Member Telecom

Clinical Tests
- Clinical Tests
- Clinical Test Results/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Diagnosis
- Encounter Disposition
- Encounter Identifier
- Encounter Location
- Encounter Time
- Encounter Type

Facility Information
- Facility Address
- Facility Identifier
- Facility Name
- Facility Type

Genomics
- **Blood Genotype (NEW) (A) & (B)**
- **Variant Interpretation (NEW) (A) & (B)**

Goals and Preferences
- Patient Goals

Health Status Assessments
- Disability Status
- Functional Status
- Health Concerns
- Mental/Cognitive Status
- **Pain Assessment (NEW) (B)**

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Dose
- Dose Unit of Measure
- Medications

Patient Demographics
- Current Address
- Date of Birth
- Date of Death
- First Name

Patient Demographics/Information (Con't)
- Last Name
- Middle Name (including middle initial)
- Previous Name Suffix
- Previous Name
- Email Address
- Ethnicity
- Phone Number
- Race
- Sex

Problems
- Date of Diagnosis
- Date of Resolution
- **Condition Evidence (NEW) (B)**
- Problems

Procedures
- Performance Time
- **Blood Transfusion Date and Time (NEW) (B)**
- Procedures

Provenance
- Author
- Author Role
- Author Organization

Vital Signs
- BMI Percentile (2-20 years)
- Body Height
- Body Temperature
- Body Weight
- Pulse Oximetry
- Diastolic Blood Pressure
- Systolic Blood Pressure

USCDI+ SCD Draft Data Elements (NEW) (1 of 2)

USCDI Data Class	Data Element	Description
Biologically Derived Product	Blood Transfusion Product Antibody	Blood protein produced in response to and counteracting an antigen.
Biologically Derived Product	Blood Transfusion Product Antigen	Proteins or sugars expressed on red blood cells are used to determine an individual's blood group.
Biologically Derived Product	Blood Transfusion Product Blood Type	Classification of blood based on the presence and absence of antibodies and inherited antigenic substances on the surface of red blood cells.
Biologically Derived Product	Blood Transfusion Product Name	The name of the blood product originating from a human intended to be transplanted or infused into another (possibly the same) human (e.g., red blood cells, platelets, fresh frozen plasma).
Genomics	Blood Genotype	The genetic makeup of an individual's blood group, specifically the blood type and Rh factor.
Health Status Assessment	Pain Assessment	Evaluation of a patient's emotional distress or physical discomfort utilizing a standardized instrument.

USCDI+ SCD Draft Data Elements (NEW) (2 of 2)

USCDI Data Class	Data Element	Description
Medications	Medication List	Set of medications a patient has taken or is taking, that include includes active, historical, and future (planned) medication.
Medications	Medication Statement	A record of a medication that is being consumed by a patient, including indicating that the patient may be taking the medication now, has taken the medication in the past, or will be taking the medication in the future.
Problems	Condition Evidence	Supporting evidence that is the basis for determining the condition.
Procedures	Blood Transfusion Date & Time	Date that the blood product originating from a human was or is intended to be transplanted or infused into another (possibly the same) human (e.g., red blood cells, platelets, fresh frozen plasma).

USCDI+ SCD Proposed Data Elements (Use Case A)

Care Plan	Care Team Members	Facility Information
Assessment and Plan of Treatment Care Plan **(NEW)**	Care Team Member Identifier Care Team Member Locator Care Team Member Name Care Team Member Role Care Team Member Telecom	Facility Address Facility Identifier Facility Name Facility Type
Genomics	**Laboratory**	**Medications**
Blood Genotype **(NEW)** Variant Interpretation	Tests Values/Results	Dose Medications
Patient Demographics/Information	**Problems**	**Provenance**
Current Address Date Of Birth Date of Death First Name Last Name Middle Name(including middle initial) Name Suffix Previous Name Email Address Ethnicity Phone Number Race Sex	Date of Diagnosis Date of Resolution Condition Evidence Problems	Author Author Organization Author Role Author Time Stamp

USCDI+ SCD Proposed Data Elements (Use Case B) (1 of 2)

Allergies and Intolerances	Biologically Derived Product	Care Plan
Drug Class Allergy Intolerance Medication Allergy Intolerance Non-Medication Allergy Intolerance Reaction	Blood Transfusion Product Antibody **(NEW)** Blood Transfusion Product Antigen **(NEW)** Blood Transfusion Product Blood Type **(NEW)** Blood Transfusion Product Name **(NEW)**	Assessment and Plan of Treatment Care Plan
Care Team Members	**Clinical Tests**	**Diagnostic Imaging**
Care Team Member Identifier Care Team Member Location Care Team Member Name Care Team Member Role Care Team Member Telecom	Clinical Tests Clinical Test Result/Report	Diagnostic Imaging Test Diagnostic Imaging Report
Encounter Information	**Facility Information**	**Genomics**
Encounter Diagnosis Encounter Disposition Encounter Identifier Encounter Location Encounter Time Encounter Type	Facility Address Facility Identifier Facility Name Facility Type	Blood Genotype **(NEW)** Variant Interpretation **(NEW)**

USCDI+ SCD Proposed Data Elements (Use Case B) (2 of 2)

Goals and Preferences	Health Status Assessments	Immunizations
Patient Goals	Disability Status Functional Status Health Concerns Mental/Cognitive Status Pain Assessment **(NEW)**	Immunizations
Laboratory	**Medications**	**Patient Demographics/Information**
Tests Values/Results	Dose Dose Unit of Measure Medications	Current Address Date of Birth Date of Death First Name Last Name Middle Name (including middle initial) Name Suffix Previous Name Email Address Ethnicity Phone Number Race Sex
Problems	**Procedures**	**Vital Signs**
Condition Evidence **(NEW)** Date of Diagnosis Date of Resolution SDOH Problems/Health Concerns	Performance Time Blood Transfusion Date and Time **(NEW)** Procedures	BMI Percentile (2-20 years) Body Height Body Temperature Body Weight Pulse Oximetry Diastolic Blood Pressure Systolic Blood Pressure

How Can You Help? Comment on Draft Data USCDI+SCD Element List

ONC has recently published the draft USCDI+ SCD data element list, which will be open for a public 45-day comment period until July 25, 2026, at 5:00 PM. A user account is required to submit your feedback.

1. To create an account, click the link to access the USCDI+ platform. Click ‘log in’ at the top right of the platform. Look under ***other Use Cases.***
2. Read the USCDI+ SCD knowledge article, which contains key questions to guide your feedback on the data elements.
3. Review the new draft data element lists under the other use cases category on the platform.
4. Select the "SCD Diagnosis or SCD Emergency Care comment period option.
5. Submit your comments on the new draft data elements.

USCDI+ Platform



Contact Information

Pilot Testing Opportunities email: **USCDI_plus@kahuina.com**

For questions about the draft SCD dataset, please email **USCDI.Plus@hhs.gov**

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https://www.youtube.com/user/HHSONC

Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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Resources

OMH
U.S. Department of Health and Human Services
Office of Minority Health

WORLD SICKLE CELL DAY

Resources

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

- CureSCi Metadata Catalog
- Cure Sickle Cell Initiative
- NHLBI Cure Sickle Cell Initiative Common Data Elements

Health Resources & Services Administration (HRSA)

- Sickle Cell Disease Programs | MCHB

Office of the National Coordinator for Health Information Technology (ONC)

- USCDI+ Platform
- Platform User Guides- Account Creation, Commenting, Site Navigation
- Overview Summary of the USCDI+ SCD Dataset and the Request for Public Feedback
- New Use Cases, Data Classes, and Specific Data Elements

Center for Medicare & Medicaid Innovation (CMMI)

- CGT (Cell and Gene Therapy Access) Model

OMH U.S. Department of Health and Human Services Office of Minority Health

WORLD SICKLE CELL DAY

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Research That Heals:

Partnering with Patients to Transform SCD Care

June 25-26, 2026

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Hosted By: National Heart, Lung, and Blood Institute (NHLBI), in partnership with the Sickle Cell Disease Association of America (SCDAA)

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WORLD SICKLE CELL DAY



Question & Answers

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WORLD SICKLE CELL DAY

Questions & Answers



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Closing Remarks

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U.S. Department of Health & Human Services

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Thank You!

Follow **@MinorityHealth** on **X** and **YouTube**, and **@HealthGov** on **Facebook** and **Instagram**, to learn about new resources, initiatives, and events.

Visit **minorityhealth.hhs.gov** for health data and resources related to racial and ethnic minority populations and American Indians/Alaska Natives.

Email us at **MinorityHealthInfo@hhs.gov or scan our QR code** and let us know what part of today's session you found most useful and if you have ideas for how we can improve future events.

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