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FDA REMS Programs List: ETASU, Duties and Integration

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Executive Summary

The official **FDA REMS programs list** is maintained through **REMS@FDA** and FDA's public dashboard. The accessible reports page showed **68 current programs** when accessed on **October 15, 2026**.

(www.accessdata.fda.gov) FDA reported **56 programs with elements to assure safe use (ETASU)**, or **82%**, and **12 communication-plan-only programs**, or **18%**. (www.accessdata.fda.gov) These are descriptive program counts, rather than drug counts, safety rankings or a trend series. This report supplies the current program-name index, a selected participant-duty crosswalk and an integration matrix for implementation teams.

The central finding is that certification, enrollment, monitoring and authorization need separate operational records. **CAMZYOS** requires prescriber certification, pharmacy certification and patient enrollment. (www.camzyosrems.com) (www.camzyosrems.com) **SPRAVATO** certifies healthcare settings and pharmacies, with patient enrollment applying to outpatient treatment. (www.spravatorems.com) (www.spravatorems.com) **LEMTRADA** requires a healthcare facility to enroll separately from its prescriber. (www.lemtradarems.com) A platform organized around a single "REMS registered" field would obscure these distinctions. The detailed crosswalk identifies the actor, required evidence and transaction checkpoint for each selected example.

Integration options also have defined boundaries. HL7's published **US Medication REMS FHIR guide, version 2.0.0, STU 2**, addresses provider workflows. (hl7.org) It supports structured interactions and form exchange, while detailed pharmacy interactions sit outside its scope. (hl7.org) NCPDP separately documents REMS observation elements in SCRIPT transactions. (www.ncpdp.org) These standards support implementation planning; they do not establish universal production adoption. The proposed matrix identifies triggering events, source evidence, record ownership, exchange direction and audit artifacts.

The editorial date is **October 9, 2026**, but no historical snapshot for that date was recovered. Current findings are labeled with the later access date. FDA updates the dashboard weekly, although its exact refresh timestamp was unavailable during retrieval. (www.fda.gov) Complete downloadable version records were also unavailable, so whole-inventory counts by certification or enrollment duty are withheld. The operational conclusion is to maintain a versioned requirements registry and verify the current approved document before configuring each workflow. The dashboard's stated descriptive limits guide interpretation of the inventory.

Introduction and Background

A useful **FDA REMS programs list** connects each program to the people, evidence and decisions it governs. Risk Evaluation and Mitigation Strategies (REMS) can impose different requirements on prescribers, dispensers, healthcare settings and patients. The observed instructions assign different duties to individuals, facilities and pharmacies. A portfolio platform therefore needs a program-specific rule model.

(www.lemtradarems.com) (qsymiarems.com)

The practical audience includes program owners, pharmacovigilance and medical-information leaders, **specialty pharmacies**, patient-services teams and architects. Their decisions concern certification, enrollment, monitoring submissions, authorization and records. For example, **CAMZYOS** separately requires prescriber certification, pharmacy certification and patient enrollment, while **SPRAVATO** organizes important responsibilities around certified treatment settings. (www.camzyosrems.com) (www.camzyosrems.com) (www.spravatorems.com)

This report supplies a complete current program-name index and a deliberately bounded operational crosswalk. The full index records observable ETASU presence and explicit shared-system designations. The detailed crosswalk covers selected programs whose participant instructions were retrieved. Its blank or unestablished fields are evidence gaps, never permission to bypass a control.

The editorial publication anchor is **October 9, 2026**; research access occurred **October 15, 2026**. These are report dates. No historical dashboard snapshot for the earlier date was recovered. Current observations are consequently labeled by access date, and approved-document dates are identified separately.

The consultancy perspective is operational. IntuitionLabs describes enterprise implementation and integration among its services; this report applies that perspective to evidence movement and system boundaries.

(intuitionlabs.ai) It provides workflow analysis for organizational implementation. Program-specific clinical decisions belong with the treating professionals and the current approved materials.

Methodology and Source Control

The source hierarchy starts with **REMS@FDA**, then the current approved REMS document, then participant materials and official program websites. The Congressional Research Service explains that FDA database accessibility varies with scope, data types and search capabilities, and explicitly points readers to the REMS dashboard alongside the approved-program database. (www.everycrsreport.com) (www.everycrsreport.com)

FDA's documented data model separates **REMSID**, the program key, from **VersionID**, the version key. It also defines flags for current approval, release, movement to a shared system, ETASU, prescriber certification, dispenser certification, patient enrollment and training. These are useful join fields. Their documented existence does not mean this research successfully downloaded their underlying records.

(www.accessdata.fda.gov)

A maintainable inventory should retain the following fields:

- **Identity:** FDA program key, display name and covered products.
- **Version:** version key, approval or revision date and effective operational date.

- **Status:** current approval, release and movement to a shared system.
- **Participants:** prescriber, dispenser, setting, patient and applicant. The roles model should preserve their distinct identities. (hl7.org)
- **Controls:** certification, enrollment, training, monitoring and authorization. For example, Qsymia's certification process identifies an authorized representative and training assessment. (qsymiarems.com)
- **Evidence:** source document, exact requirement location and retained artifact. HL7 describes storing a DocumentReference in the patient record. (hl7.org)
- **Verification:** retrieval date, verification owner and unresolved questions.
- **Change history:** previous value, new value and the decision approving implementation. The inventory should also preserve routing to the correct administrator. (hl7.org)

These are proposed inventory-design fields. FDA's schema establishes several underlying identifiers and flags; the evidence and implementation-governance fields are analyst recommendations.

Three retrieval limitations matter. The interactive dashboard returned an unusable shell, and the permitted fallback could not retrieve it. The downloadable data route also failed to supply the complete version records. Individual program records and several approved documents remained accessible. Therefore this report uses the current FDA list for population membership and clearly identified document or program-site evidence for duties.

A weekly maintenance process should capture the published list, compare keys and versions, retrieve changed approved materials, and review changes before updating operational rules. Because the dashboard timestamp was unavailable, a refresh job should record both retrieval time and the source's own timestamp whenever exposed. Retaining the source file and its checksum is a recommended audit practice.

FDA expressly says the dashboard is descriptive and is not intended for trend analysis or cross-comparisons. Accordingly, the calculations below describe one observed population and a selected verification sample. They do not measure changes over time or compare the safety of products. (www.fda.gov)

Active FDA REMS Program Inventory

Table 1 is the current FDA program index, accessed **October 15, 2026**. Every row belongs to the currently approved list. **Y** means presence was directly captured; **N** means ETASU absence was captured; **?** means the field was not established. In the shared-system column, only affirmative designations were captured. A question mark does not mean a single-product program. The common official record source for every row is FDA's current list. (www.accessdata.fda.gov)

Program	ETASU	Shared system established
Adasuve	Y	?
Alvimopan Shared System REMS	Y	Y
Aqvesme	Y	?
Aveed	Y	?

Program	ETASU	Shared system established
Bildyos	N	?
BKEMV	Y	?
Blenrep	Y	?
Boncresa	N	?
Bosaya	N	?
Bosentan	Y	Y
Brixadi	Y	?
Buprenorphine Transmucosal Products for Opioid Dependence (BTOD)	Y	Y
Camzyos	Y	?
Conexence	N	?
Copiktra	N	?
Elrexio	Y	?
Empaveli	Y	?
Enoby	N	?
Epysqli	Y	?
Fabhalta	Y	?
Filspari	Y	?
Fintepla	Y	?
Hepzato	Y	?
Isotretinoin iPLEDGE	Y	Y
Jubbonti	N	?
Juxtapid	Y	?
Lemtrada	Y	?
Lenalidomide	Y	Y
Lumryz	Y	?
Lynozyfic	Y	?
Mifepristone	Y	Y
Miudella	Y	?

Program	ETASU	Shared system established
Myalept	Y	?
Myqorzo	Y	?
Nexplanon	Y	?
Opioid Analgesic REMS	?	?
Ospomyv	N	?
Osvyrti	N	?
Palforzia	Y	?
Palynziq	Y	?
Phentermine and Topiramate Extended-Release Capsules	Y	Y
Piasky	Y	?
Ponlinsi	N	?
Probuphine	Y	?
Prolia	N	?
PS-Pomalidomide	Y	Y
Qsymia	Y	?
Siliq	Y	?
Sodium Oxybate	Y	Y
Spravato	Y	?
Stoboclo	N	?
Sublocade	Y	?
Tecvayli and Talvey	Y	?
Thalidomide REMS	Y	Y
Tolvaptan for ADPKD Shared System REMS	Y	Y
Transmucosal Immediate-Release Fentanyl (TIRF) Products	Y	Y
Turalio	Y	?
Tyruko	Y	?
Tysabri	Y	?
Ultomiris and Soliris	Y	?

Program	ETASU	Shared system established
Vanflyta	Y	?
Vigabatrin	Y	Y
Voydeya	Y	?
Xiaflex	Y	?
Xywav and Xyrem	Y	?
Zenbexus	Y	?
Zilbrysq	Y	?
Zyprexa Relprevv	Y	?

The index covers **programs**, rather than a unique-drug count. Product names, ingredients and program names should remain separate entities in an implementation database. Several products can be covered by one operational program: the PS-Pomalidomide site, for example, explicitly includes POMALYST and generic pomalidomide products. (www.ps-pomalidomiderems.com)

The question mark on the Opioid Analgesic row preserves an uncaptured row-level observation. FDA's aggregate ETASU count is available separately; it is not used to manufacture that missing cell. Likewise, shared-system membership should be populated from the actual flag or approved record, rather than inferred from a recognizable product name.

Table 2 adds the operational crosswalk. **P** means prescriber, **D** means pharmacy or dispenser, **H** means healthcare setting, and **Pt** means patient. “Not established” describes this research's evidence boundary. The cited links are opened official documents or operational sources. All rows were verified during the same research access date; a linked operational page is not represented as the latest approved REMS document.

Program	Participant certification or enrollment	Testing, monitoring or documentation	Dispensing or administration check	Official source
CAMZYOS	P and D certified; Pt enrolled	Echocardiography and patient-status documentation	Authorization for each prescription	Approved document (www.accessdata.fda.gov)
SPRAVATO	H and D certified; outpatient Pt enrolled	Monitoring form; setting records	Verify outpatient enrollment and receiving-setting certification	Approved document (www.accessdata.fda.gov)
Xywav and Xyrem	P and D certified; Pt enrolled	Documented safe-use conditions	Certified central-pharmacy distribution to enrolled patients	Official prescriber brochure (www.xywavxyremrems.com) (www.xywavxyremrems.com)
Lenalidomide	P and D certified; Pt enrolled	Counseling checklist and prescription documentation	Separate prescription authorization and dispensing confirmation	Official pharmacy guide (www.lenalidomiderems.com) (www.lenalidomiderems.com)

Program	Participant certification or enrollment	Testing, monitoring or documentation	Dispensing or administration check	Official source
FINTEPLA	P and outpatient D certified; Pt enrolled	Cardiac monitoring and patient-status submissions	P certification and Pt enrollment/authorization	Official outpatient-pharmacy form (www.finteplarems.com)
Tolvaptan for ADPKD	P and D certified; Pt enrolled	Hepatic monitoring and patient-status forms	Authorization for each outpatient prescription	Official shared-system program (www.tolvaptanadpkdsharedrems.com)
Thalidomide REMS	P and D certified; Pt enrolled	Counseling, surveys and confirmation records	Document dispensing confirmation number and date	Approved document (www.accessdata.fda.gov)
Isotretinoin iPLEDGE	P and D enrolled and activated	Detailed testing controls require current-material review	Active program participation required	Official program (ipledgeprogram.com) (ipledgeprogram.com)
PS-Pomalidomide	P and D certified; Pt enrolled	Pregnancy-test verification where applicable	Prescription authorization plus D confirmation	Prescriber instructions (www.ps-pomalidomiderems.com) (www.ps-pomalidomiderems.com) (www.ps-pomalidomiderems.com)
PALYNZIQ	P and D certified; Pt enrolled	Documented education and safe-use conditions	Verify documented conditions before dispensing	Official program (www.palynziqrems.com) (www.palynziqrems.com)
LEMTRADA	P, H, D and Pt enrolled	Baseline-lab, status and infusion forms	H enrollment is separate from P enrollment	Official program and forms (www.lemtradarems.com) (www.lemtradarems.com)
Tysabri / TOUCH	P, infusion sites, associated pharmacies and Pt enrolled	Pre-infusion checklist	Confirm current patient authorization before infusion	Official TOUCH instructions (www.touchprogram.com) (www.touchprogram.com)
Qsymia	D certified; other actors not established here	Authorized representative, training and assessment	Certified-pharmacy distribution	Official pharmacy instructions (qsymiarems.com) (qsymiarems.com)
Tecvayli and Talvey	P certification checked by dispensing actor	Additional duties require current-document review	Authorization under the documented first-fill-by-that-dispensing-entity condition	Manufacturer medical information (www.jnjmedicalconnect.com)

The crosswalk is an implementation starting point. Its purpose is to expose differences worth modeling, including site enrollment, patient authorization and separate prescription-versus-dispensing numbers. It is not a substitute for a complete requirement extraction from each current approved document.

Participant Duties and ETASU

Elements to assure safe use (ETASU) are statutory categories, not interchangeable workflow labels. The underlying statute distinguishes the following controls. (www.govinfo.gov)

- **A, prescribers:** particular training, experience or special certification. (www.govinfo.gov)
- **B, dispensers:** special certification for pharmacies, practitioners or healthcare settings that dispense. (www.govinfo.gov)
- **C, settings:** dispensing only in specified healthcare settings. (www.govinfo.gov)
- **D, safe-use evidence:** documentation or other evidence that required conditions are met. (www.govinfo.gov)
- **E, monitoring:** specified monitoring for patients using the drug. (www.govinfo.gov)
- **F, registry:** enrollment of patients in a registry. (www.govinfo.gov)

Patient enrollment in a portal should not automatically be coded as statutory **F**. The approved CAMZYOS document explicitly lists A, B, D and E. The approved SPRAVATO document lists B, C, D, E and F. These examples show why a formal statutory classification belongs alongside the observed operational duties. (www.accessdata.fda.gov) (www.accessdata.fda.gov)

For **patients**, the inventory should distinguish registration, acknowledgment, counseling and continuing eligibility. PALYNZIQ requires enrollment and documented safe-use conditions; the program specifically includes education and availability of epinephrine among those conditions. The operational requirement is evidence that the applicable conditions were met, with clinical counseling handled by the responsible professionals. Qsymia's site separately emphasizes certified-pharmacy access, demonstrating another participant-focused distribution control. (qsymiarems.com) (www.palynziqrems.com) (www.palynziqrems.com)

For **prescribers**, certification can involve an application, training and a knowledge assessment. FINTEPLA requires a submitted prescriber knowledge assessment and enrollment form. (www.finteplarems.com) LEMTRADA specifies an eight-question assessment and separately requires the prescriber's healthcare facility to enroll when it dispenses or administers the product. (www.lemtradarems.com) (www.lemtradarems.com) An individual credential should therefore not populate the setting's eligibility field.

For **pharmacies**, counseling and authorization are separate objects. Lenalidomide instructions require a confirmation number before dispensing and an Education and Counseling Checklist. The PS-Pomalidomide guide likewise requires the pharmacy's confirmation number. A prescriber's authorization should remain a distinct field from the dispenser's confirmation. The prescribing workflow includes its own certified-prescriber participation in PS-Pomalidomide. (www.ps-pomalidomiderems.com) (www.lenalidomiderems.com) (www.ps-pomalidomiderems.com)

For **healthcare settings**, event timing matters. SPRAVATO's program overview specifies submission of the outpatient Patient Monitoring Form within seven days after every dose. (www.spravatorems.com) TOUCH requires its pre-infusion checklist to be submitted within one business day of the visit. (www.touchprogram.com) A system should preserve the administration event, submission deadline and receipt acknowledgment separately.

For **sponsors and program administrators**, the evidence burden includes maintaining the program's operational infrastructure and records. The approved Thalidomide REMS requires a validated, secure participant database. SPRAVATO's approved document requires public access to a database of certified settings and pharmacies. These are concrete requirements in those documents, rather than universal capabilities inferred for every REMS. (www.accessdata.fda.gov) (www.accessdata.fda.gov)

System Interactions and Audit Evidence

A REMS integration should identify the triggering event before choosing an interface. Health Level Seven International (HL7) publishes the **US Medication REMS Fast Healthcare Interoperability Resources (FHIR) implementation guide**, version **2.0.0**, Standard for Trial Use 2 (STU 2), dated November 17, 2025. It focuses on provider ordering and encounter workflows. Publication of a standard does not establish adoption by every program or electronic health record (EHR). (hl7.org) (hl7.org)

The guide combines **clinical decision support (CDS) Hooks, Substitutable Medical Applications and Reusable Technologies (SMART) App Launch**, and REMS information carried in prescriptions using the **National Council for Prescription Drug Programs (NCPDP) SCRIPT** standard. Its detailed pharmacy interactions are outside the guide's scope. NCPDP separately describes observation elements added to REMS transactions in SCRIPT version 2023011. (hl7.org) (hl7.org) (www.ncdp.org)

Table 3 maps verified duty patterns to proposed system capabilities. It is an analyst-designed integration matrix. "System of record" identifies the recommended owner for that evidence type, subject to the actual program's operating model. Directions and retained artifacts are implementation recommendations; the citations establish the underlying duty or standards pattern.

Trigger and actor	Duty and common capability	Source evidence	Recommended system of record	Exchange direction	Recommended audit artifact
Certification application, P or D	Identity, portal, training and assessment	Completed assessment and enrollment instructions (www.finteplarems.com) (qsymiarems.com)	REMS administrator for certification status	Participant to administrator; status returned	Submitted form, assessment version, decision and timestamp
Patient enrollment, P/designee and Pt	Portal and case management	Enrollment/status documentation (www.camzyosrems.com) (www.palynziqrems.com)	REMS administrator for program enrollment	Care team to administrator; acknowledgment to care team	Signed or acknowledged enrollment, case identifier and receipt
Prescription finalized, P	EHR decision support and form launch	Order-sign trigger pattern (hl7.org)	EHR for order; administrator for REMS case	EHR to administrator, with structured response	Order reference, request context and returned task/case
Monitoring review, P	Lab feed and case management	FINTEPLA status form; tolvaptan monitoring resources (www.finteplarems.com) (www.jynarquehcp.com)	Clinical system for result; administrator for accepted status	Clinical evidence to authorized reviewer; status to administrator	Result provenance, review record, submitted form and acknowledgment

Trigger and actor	Duty and common capability	Source evidence	Recommended system of record	Exchange direction	Recommended audit artifact
Prescription prepared, D	Dispensing authorization and portal	Confirmation or authorization requirement (www.lenalidomiderems.com) (www.tolvaptanadpkdsharedrems.com)	Administrator for authorization; pharmacy for dispense	D query to administrator; authorization returned	Request/response, authorization number, time and rule version
Dose administered, H	Monitoring workflow and case management	SPRAVATO monitoring form and TOUCH checklist (www.spravatorems.com) (www.touchprogram.com)	Setting for encounter; administrator for received form	Setting to administrator	Administration time, completed form, submission time and receipt
Staff training completed, pharmacy	Training records and audit log	FINTEPLA pharmacy staff-training documentation (www.finteplarems.com)	Pharmacy training record	Training evidence to designated pharmacy representative	Staff identity, training version, completion record and review
Completed REMS application workflow, provider system	Document storage and structured forms	DocumentReference and QuestionnaireResponse patterns (hl7.org) (hl7.org)	EHR for stored reference; administrator for submitted response	App to administrator; document reference to EHR	Response identifier, document version and storage acknowledgment

The important architectural distinction is between a clinical result, a submitted form, and an accepted authorization. They represent different events and can arrive at different times. For example, FINTEPLA's pharmacy instructions require confirmation that the prescriber is certified and the patient is enrolled and authorized. A laboratory-result feed alone does not establish those other conditions. (www.finteplarems.com)

Identity is another boundary. The Centers for Medicare & Medicaid Services (CMS) warns that issuance of a **National Provider Identifier (NPI)** does not validate licensure or credentials. Use an NPI as an identifier, and maintain separately sourced program-certification status with its provenance. (download.cms.gov)

A practical design review should ask:

- **Routing:** which administrator owns the requested program or case? HL7 describes intermediary routing. (hl7.org)
- **Authority:** which response constitutes the program's dispensing decision? Lenalidomide uses a pharmacy confirmation number. (www.lenalidomiderems.com)
- **Freshness:** how long is evidence usable under the specific program? PS-Pomalidomide documents prescription-supply and refill constraints. (www.ps-pomalidomiderems.com)
- **Failure handling:** where are rejected, incomplete and timed-out submissions worked? HL7 allows a query of the individual patient's REMS process status. (hl7.org)
- **Reconciliation:** how are duplicate submissions and delayed acknowledgments resolved? Multiple HL7 workflow hooks should avoid duplicate provider requests. (hl7.org)

- **Retention:** can the organization reconstruct the evidence available at the decision? FINTEPLA's pharmacy form includes recordkeeping commitments. (www.finteplarems.com)

These are engineering review questions, rather than claims that a single retention period or interface applies across the portfolio.

Shared Systems and Change Control

A **shared-system REMS** should be modeled as a program relationship connecting covered products and participating applicants. The official PS-Pomalidomide site includes both branded and generic products. JYNARQUE's manufacturer directs prescribers to the Tolvaptan for ADPKD Shared System REMS. The latter explicitly limits its scope to tolvaptan products indicated for autosomal dominant polycystic kidney disease (ADPKD). Ingredient matching alone is therefore an inadequate routing rule. (www.ps-pomalidomiderems.com) (www.jynarquehcp.com) (www.tolvaptanadpkdsharedrems.com)

The central-pharmacy arrangement documented for Xywav and Xyrem also illustrates why an architecture needs a distribution-model field. Its brochure specifies dispensing through the specially certified central pharmacy to enrolled patients with documented safe-use conditions. Multiple product names do not by themselves establish FDA shared-system classification. (www.xywavxyremrems.com) (www.xywavxyremrems.com)

Change management should separate the regulatory action from its implementation schedule. FDA defines **revisions** as editorial changes that leave specified risk information, compliance actions and supporting materials unaffected. Its internal procedure distinguishes revisions, minor modifications and major modifications, with different submission and implementation paths. Regulatory affairs should classify the actual change against current guidance before an operational rule is released. (www.fda.gov) (www.fda.gov)

A useful change record distinguishes:

- **Editorial revision:** update wording or presentation and assess affected artifacts.
- **Requirement modification:** identify actors, events and evidence that change.
- **Implementation date:** record when the revised workflow becomes operational.
- **Product movement:** preserve the relationship between earlier and shared-system records.
- **Release:** retire the REMS-specific control only after authoritative confirmation.
- **Evidence retention:** preserve prior versions and decisions made under them.

Several verified examples demonstrate the need for those distinctions. FDA reports that implementation of the approved iPLEDGE modifications was delayed until **November 15, 2026**. A document approval date alone would therefore be an unreliable effective-date rule for the October research window. (www.fda.gov)

FDA also reports that the Ambrisentan Shared System, Macitentan-Containing Products Shared System and Tryvio REMS were eliminated in **April 2025**. (www.fda.gov) Its separate clozapine notice states that removal was effective **June 13, 2025**. (www.fda.gov) These are status examples, not a complete released-program inventory. A program missing from the active table must be investigated rather than automatically labeled released.

For architecture, a release should trigger an approved configuration change and preserve the prior decision history. The applicable prescribing information and clinical responsibilities require their own review.

Data Analysis and Evidence

FDA's accessible Reports & Data Files page reported **68 current REMS**, of which **56, or 82%**, included ETASU and **12, or 18%**, were communication-plan-only programs, when accessed on October 15, 2026. (www.accessdata.fda.gov) The displayed percentages are FDA's rounded figures. These are program counts, not counts of products, prescriptions or participants.

The complete index above contains the same number of program rows. Its uncaptured Opioid Analgesic ETASU cell remains unknown, even though the aggregate is reported. Keeping row-level uncertainty separate from a published aggregate prevents a reconciliation check from becoming invented source data.

Current whole-population counts for prescriber certification, dispenser certification, patient enrollment and training could not be calculated because the version-record export was not obtained. Those schema definitions are not measurements of populated values. Readers planning capacity should request and reconcile the actual current records before using these dimensions as portfolio totals.

A smaller calculation is possible from the **six-program verification sample**, calculated from the corresponding sourced rows in Table 2: CAMZYOS, SPRAVATO, Lenalidomide, FINTEPLA, Xywav/Xyrem and Tolvaptan for ADPKD. The initially read FDA records and the operational sources retained in Table 2 establish dispenser certification and patient enrollment in each, with SPRAVATO's enrollment requirement applying to outpatients. Five list separate prescriber certification; SPRAVATO assigns the relevant certification duties to settings and pharmacies. These are direct counts from the selected records, with no population estimate. (www.accessdata.fda.gov) (www.accessdata.fda.gov) (www.lenalidomiderems.com) (www.finteplarems.com) (www.xywavxyremrems.com) (www.tolvaptanadpkdsharedrems.com) The Lenalidomide guide is dated December 2022 and remains linked by its official resource page; its date is not represented as a current approval date. (www.lenalidomiderems.com)

The sample also exposes timing dimensions that a portfolio count would obscure. FINTEPLA's instructions specify cardiac monitoring every **six months** during treatment and once **three to six months** after discontinuation. (www.finteplarems.com) TOUCH separately describes treatment authorization every **six months**. (www.touchprogram.com) PS-Pomalidomide additionally limits prescriptions to a **28-day supply**, without automatic refills. (www.ps-pomalidomiderems.com) Similar intervals and quantities refer to different activities and cannot safely share an undifferentiated "next REMS due" field.

Likewise, Tolvaptan for ADPKD's Patient Status Form is submitted every **three months** for the first **eighteen months**, then every **six months**. (www.tolvaptanadpkdsharedrems.com) That reporting schedule should remain distinct from the underlying clinical monitoring schedule. LEMTRADA's setting enrollment renews every **two years**, adding a participant-credential lifecycle to the patient-event model. (www.lemtradarems.com)

For measurement, recommended denominators include required authorizations, due monitoring submissions, applications awaiting review and credentials due for renewal. Report completion against those explicitly defined obligations. Do not combine patient, pharmacy and setting counts into an apparent completion rate without defining what each counted unit represents.

Implications and Future Directions

The near-term opportunity is a controlled requirements registry linked to the systems carrying out the work. HL7 describes REMS administrators maintaining enrollment and certification repositories, and intermediaries routing requests to the correct administrator. These are useful patterns for separating an enterprise view from the program's own authoritative status. (hl7.org) (hl7.org)

Standards scope should remain visible in procurement. HL7 places patient-directed enrollment and additional EHR/pharmacy interactions in its future-scenario discussion. Those passages support roadmap questions, rather than claims of generally available production capabilities. The guide also advises distinct purposes for multiple workflow hooks so they do not create duplicate provider requests. (hl7.org) (hl7.org)

Structured regulatory submission is a separate workstream. FDA's guidance specifies **Structured Product Labeling (SPL)** for REMS document submissions, and its technical conformance guide provides standardized language for common requirements. These resources concern submitted REMS content. They do not establish that a program exposes a real-time enrollment, laboratory or dispensing interface. (www.fda.gov) (www.fda.gov)

An implementation checklist should therefore cover:

- **Reconcile identity:** program key, product mapping and participant identifiers. Treat the NPI as an identifier with defined limitations. (download.cms.gov)
- **Verify authority:** current approved document and relevant operational materials. Requirements can be distributed across prescriber and pharmacy resources. (www.ps-pomalidomiderems.com)
- **Separate roles:** individual, organization, dispensing site and patient. LEMTRADA explicitly separates facility enrollment. (www.lemtradarems.com)
- **Model conditions:** eligibility, monitoring, authorization and evidence independently. FINTEPLA identifies patient-status documentation and treatment authorization. (www.finteplarems.com)
- **Confirm channels:** documented portal, phone, fax or supported interface. Eligible lenalidomide pharmacies can obtain confirmation numbers through its portal. (www.lenalidomiderems.com)
- **Test timing:** renewal, submission deadline and effective-date transitions. LEMTRADA requires periodic facility-enrollment renewal. (www.lemtradarems.com)
- **Exercise exceptions:** unresolved matches, duplicate events and delayed responses. The HL7 case number can help the pharmacy reference a REMS case. (hl7.org)
- **Retain evidence:** source version, submitted artifacts and accepted decisions. FINTEPLA's pharmacy form includes dispensing and training recordkeeping. (www.finteplarems.com)

The CAMZYOS document is a practical reminder that channels can remain mixed: it requires dispensing authorization online and by phone, and supports enrollment/status processes online and by fax. Procurement should ask for the supported channel and evidence receipt for each workflow. (www.accessdata.fda.gov)

IntuitionLabs describes authoritative information sources, identity, permissions and accountable operation in its information-layer approach. (intuitionlabs.ai) Applied here, those are useful design principles for connecting participant workflows to their source requirements. The implementation objective is traceability from a current

rule to the evidence and decision it produced. For pharmacy workflows, the NCPDP transaction scope and supported version should be confirmed with the actual implementation. (www.ncdp.org)

Conclusion

An operational FDA REMS inventory needs several linked layers: current program membership, product coverage, participant responsibilities, the conditions attached to a transaction, and the evidence retained after completion. This report provides the current program-name index and a sourced operational crosswalk while exposing the fields that require further document extraction.

The examples show why certification, enrollment and authorization deserve separate records. An individual prescriber's status does not establish a facility's enrollment, a submitted monitoring form does not establish an accepted dispensing decision, and product identity alone does not establish the correct program route. Maintaining those distinctions makes reconciliation and change review more precise.

The appropriate next step is to reconcile the portfolio against the live FDA records, extract each applicable current approved document, and assign ownership for every required event. System selection can then follow a concrete workflow: who acts, what evidence they provide, who accepts it, which decision follows, and what record remains.

The access-date and completeness boundaries are part of the asset's usefulness. Population counts describe the observed list. Sample counts describe only the verified sample. Unknown control fields remain explicit until sourced. A weekly refresh process, version history and approved implementation dates can turn that bounded inventory into a maintainable operational reference.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemisData.page>
2. <https://www.camzyosremis.com/>
3. <https://www.spravatoremis.com/>
4. <https://www.lemtradaremis.com/Home/prescriber-enrollment>
5. <https://hl7.org/fhir/us/medication-rems/index.html>
6. <https://hl7.org/fhir/us/medication-rems/STU2/specification.html>
7. <https://www.ncdp.org/resources.aspx>
8. <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/risk-evaluation-and-mitigation-strategy-rems-public-dashboard>
9. <https://qsymiaremis.com/>
10. <https://intuitionlabs.ai/articles/what-is-specialty-pharmacy>
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12. https://www.everycrsreport.com/files/2025-05-19_R48133_b379a9441de586e1d65556697281b55b6ed2a3d1.html
13. <https://hl7.org/fhir/us/medication-rems/STU2/roles.html>

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15. <https://www.accessdata.fda.gov/scripts/cder/remss/index.cfm>
16. <https://www.ps-pomalidomiderems.com/products-covered/index.html>
17. https://www.accessdata.fda.gov/drugsatfda_docs/remss/Camzyos_2026_09_30_REMS_Document.pdf
18. https://www.accessdata.fda.gov/drugsatfda_docs/remss/Spravato_2026_06_24_REMS_Document.pdf
19. https://www.xywavxyremremss.com/sites/default/files/2025-07/XYWAV-XYREM_REMS_Prescriber_Brochure.pdf
20. https://www.lenalidomiderems.com/media/wp-content/uploads/LEN_Pharmacy_Guide.pdf
21. <https://www.finteparems.com/Public/GetPdf/PharmacyEnrollmentFormTemplateOutPatient.pdf>
22. <https://www.tolvaptanadpkdsharedremss.com/>
23. https://www.accessdata.fda.gov/drugsatfda_docs/remss/Thalidomide_REMS_2026_09_02_REMS_Document.pdf
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31. <https://www.jnjmedicalconnect.com/products/talvey/medical-content/tecavlyli-and-talvey-remss-dispense-authorization-rda>
32. <https://www.govinfo.gov/link/uscode/21/355-1>
33. <https://www.finteparems.com/Public/GetPdf/PrescriberEnrollmentFormTemplate.pdf>
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35. <https://www.spravatorems.com/pdfs/REMSProgramOverview>
36. <https://hl7.org/fhir/us/medication-remss/STU2/event-triggers.html>
37. <https://www.jynarquehcp.com/treatment-resources.html>
38. https://download.cms.gov/nppes/NPI_Files.html
39. <https://www.fda.gov/media/128651/download>
40. <https://www.fda.gov/media/128782/download?attachment=>
41. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/ipledge-risk-evaluation-and-mitigation-strategy-remss>
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47. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remss-document-technical-conformance-guide>

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AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

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