

Access framework for care organizations

EXAMPLE PLANNING MATERIAL. Micelle 60 is in development, to be supplied only through participating care organizations if released and approved. It is not offered for retail sale. Medicare pays \$0 for the product. This is not an executed program agreement, CMS approval or individual medical advice.

Requirement map

Domain	Organization responsibility	Micelle planning material
Governance	Assign clinical, quality, legal, privacy and operational decision rights.	Program overview and responsibility register.
Eligibility	Apply local criteria and record the physician decision.	Sample checklist for organization adaptation.
Shared decision	Record benefits, risks, goals, preferences, medicines and follow-up.	Sample discussion and follow-up structure.
Product qualification	Qualify the product and each released lot against controlled evidence.	Development product sheet and Quality Passport examples.
Supply traceability	Record receipt, storage, lot, quantity, supplying clinician and local identifier.	Sample supply-log fields.
Concerns and notices	Maintain local escalation, emergency and lot-linked communication procedures.	Public concern route and planned lot notices.
Quarterly reporting	Prepare the organization's required reports and supporting records.	Synthetic export structure without patient information.

Sample material. Each organization determines its own governance, legal, clinical, privacy, quality, safety, eligibility and reporting requirements.

Five planning stages

The stage titles, organization responsibilities and Micelle support below are sourced from the website's canonical workflow. These steps remain preparatory, not operational supply.

<p>01. Product review</p> <p>Organization: Evaluate the product definition, federal and state law, evidence and procurement suitability; keep the organization's own approval record.</p> <p>Micelle's planned support: Provide the development specification and source-linked Quality Passport examples, without claiming released-product compliance.</p>
<p>02. Organization implementation plan</p> <p>Organization: Elect the incentive if appropriate; prepare, submit and maintain a CMS-required plan covering product, eligibility, amount and frequency, safeguards, distribution and oversight. CMS approval belongs to CMS.</p> <p>Micelle's planned support: Offer an adaptable access framework and source-linked CMS crosswalk for the organization's review.</p>
<p>03. Shared decision-making</p> <p>Organization: An affiliated physician determines appropriateness, reviews medications and interactions, documents goals, preferences, risks and benefits, and plans follow-up.</p> <p>Micelle's planned support: Provide patient discussion materials, not an individual medical recommendation or eligibility decision.</p>
<p>04. Supply</p> <p>Organization: Arrange lawful procurement, inventory, storage and qualified-physician supply through the participant; do not direct beneficiaries to retail reimbursement.</p> <p>Micelle's planned support: If product is released, provide lot-labelled product and handling records under agreed arrangements; no supply service is live now.</p>
<p>05. Lot records and reporting</p> <p>Organization: Keep organization-controlled records and submit CMS-required quarterly reports; respond to requests and product notices. Do not place patient information in public examples.</p> <p>Micelle's planned support: Plan a public Quality Passport for each released lot and a checked de-identified export. The sample quarterly file is synthetic, not an actual CMS submission.</p>

Current material status

Framework, sample Quality Passport and briefing are available now for organization review; controlled product release, laboratory evidence and operational supply remain gated. The BEI is elected by an eligible participant organization, with a required CMS-approved implementation plan; the participant cannot direct beneficiaries to retail reimbursement.

Contact and sources

Request an [organization briefing](#) or email team@nwpharmatech.com. Do not include patient information. See the [CMS crosswalk](#) and [readiness register](#).