NDC 12
COORDINATION AND IMPLEMENTATION FORUM

The New NDC: Understanding FDA's Rule and Why You Need to Start Now

NACDS Total Store Expo

August 17, 2026

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One Ecosystem. One Transition. One Path Forward.

What is changing?
What is the impact?
How do you plan?
What should you do?

WHAT IS CHANGING?

NDCs Today

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National Drug Code (NDC) is FDA's standard for uniquely identifying Rx, OTC, and animal drugs in the U.S.

FFDCA requires all drugs to be registered and listed

21 CFR 207.49 requires all drugs to be identified and listed using the NDC*

21 CFR 201.25 requires the NDC to be encoded in a linear barcode on Rx drugs and OTCs commonly used in hospitals

**Alternative formats permitted for human cells, tissues, and cellular and tissue-based products (HCT/Ps).*

NDC consists of 3 segments

Labeler code – IDs manufacturer, repacker, relabeler, or private label distributor

Product code – IDs active ingredient, strength, dosage form, and other distinguishing drug characteristics

Package code – IDs package size and type

Current configurations permitted

4-4-2

5-3-2

5-4-1

5-4-2

New 12-Digit Format

Current 10-Digit (NDC10)
(Variable Format)

Format	Example
4-4-2	1234-5678-90
5-3-2	12345-678-90
5-4-1	12345-6789-0

Add Leading Zero

Future 12-Digit (NDC12)
(Standard 6-4-2 Format)

Format	Example
6-4-2	001234-5678-90
	012345-0678-90
	012345-6789-00

Image Credit: https://ndc12.com/what-is-ndc12/overview

New Barcode Rule (21 CFR § 201.25)

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Today

(c) ***What does the bar code look like? Where does the bar code go?***

(1) Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN/UCC) or Health Industry Business Communications Council (HIBCC) standards or another standard or format that has been approved by the relevant Food and Drug Administration Center Director. Additionally, the bar code must:

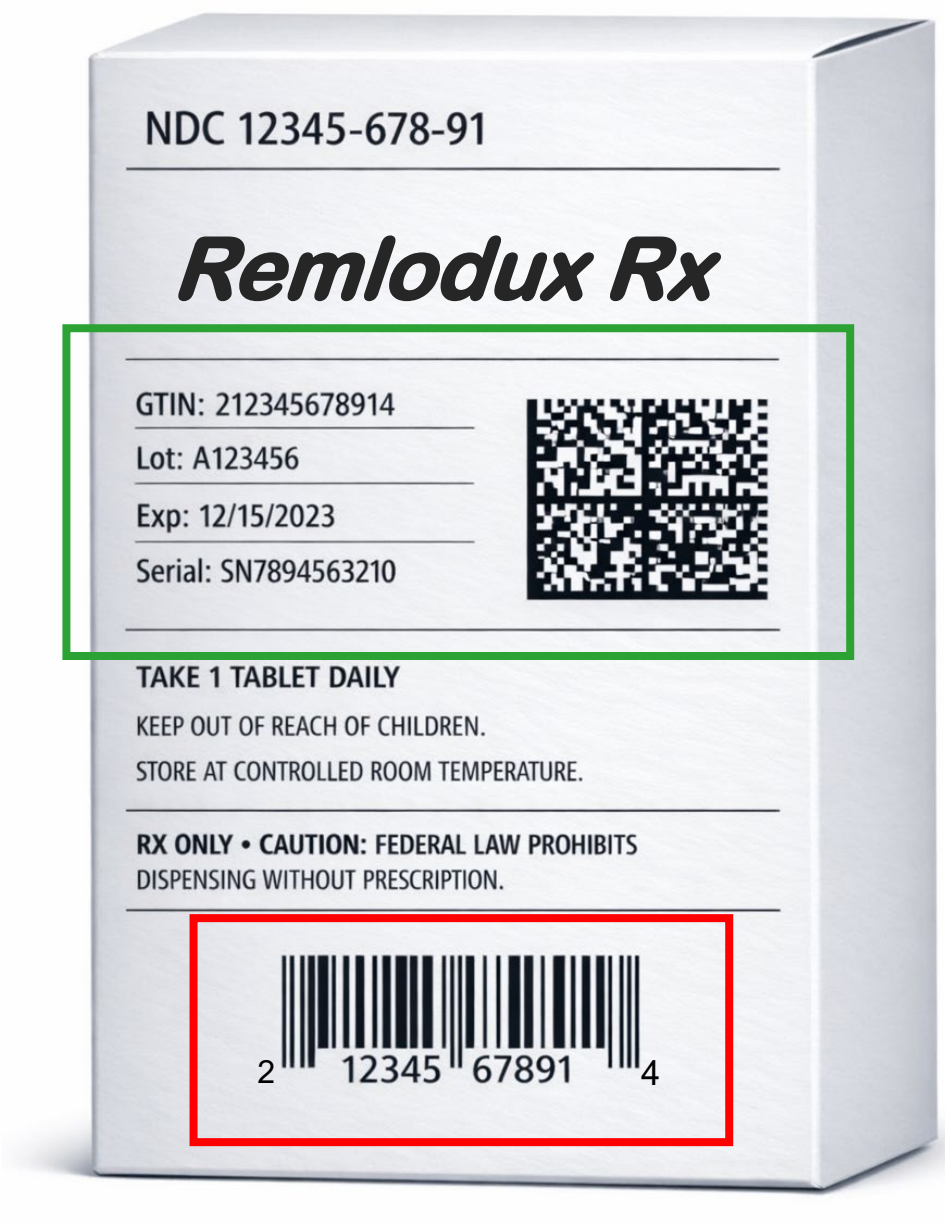
(i) Be surrounded by sufficient blank space so that the bar code can be scanned correctly; and

(ii) Remain intact under normal conditions of use.

(2) The bar code must appear on the drug's label as defined by section 201(k) of the Federal Food, Drug, and Cosmetic Act.

2033

(1) Each drug product described in paragraph (b) of this section must have a barcode that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear or nonlinear format that conforms to the standards developed by a widely recognized international standards development organization and that format and standard is recognized by the relevant Food and Drug Administration Center Director. Additionally, the barcode must:



NDC in UPC-A Linear Barcode Today

NDC = 14141-999-99

GTIN-12 = 314141999995

Image Credit: GS1 US

From One Identifier to Two

FROM:

GTIN contains NDC

GTIN
00312345678901

NDC
12345-678-90

TO:

GTIN ↔ NDC

GTIN
00312345678901

↔

NDC
012345-0678-90

KEY IMPACT:

Systems must store, exchange, and maintain both identifiers explicitly. One can no longer be inferred from the other.

Current

NDC: 14141-999-99

GTIN (01) 00314141999995
EXP 2021-12-31
Batch/Lot (10) 987654321GFEDCBA
Serial (21) 10000000234

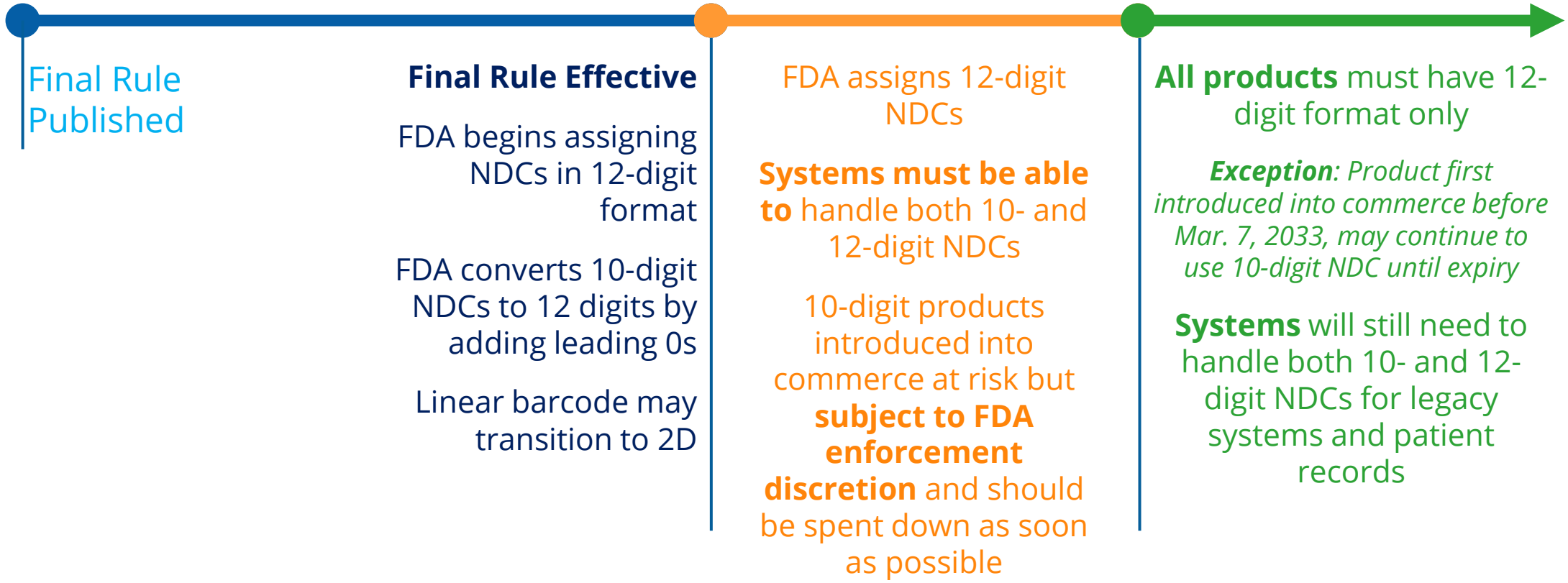
Future

NDC: 014141-0999-99

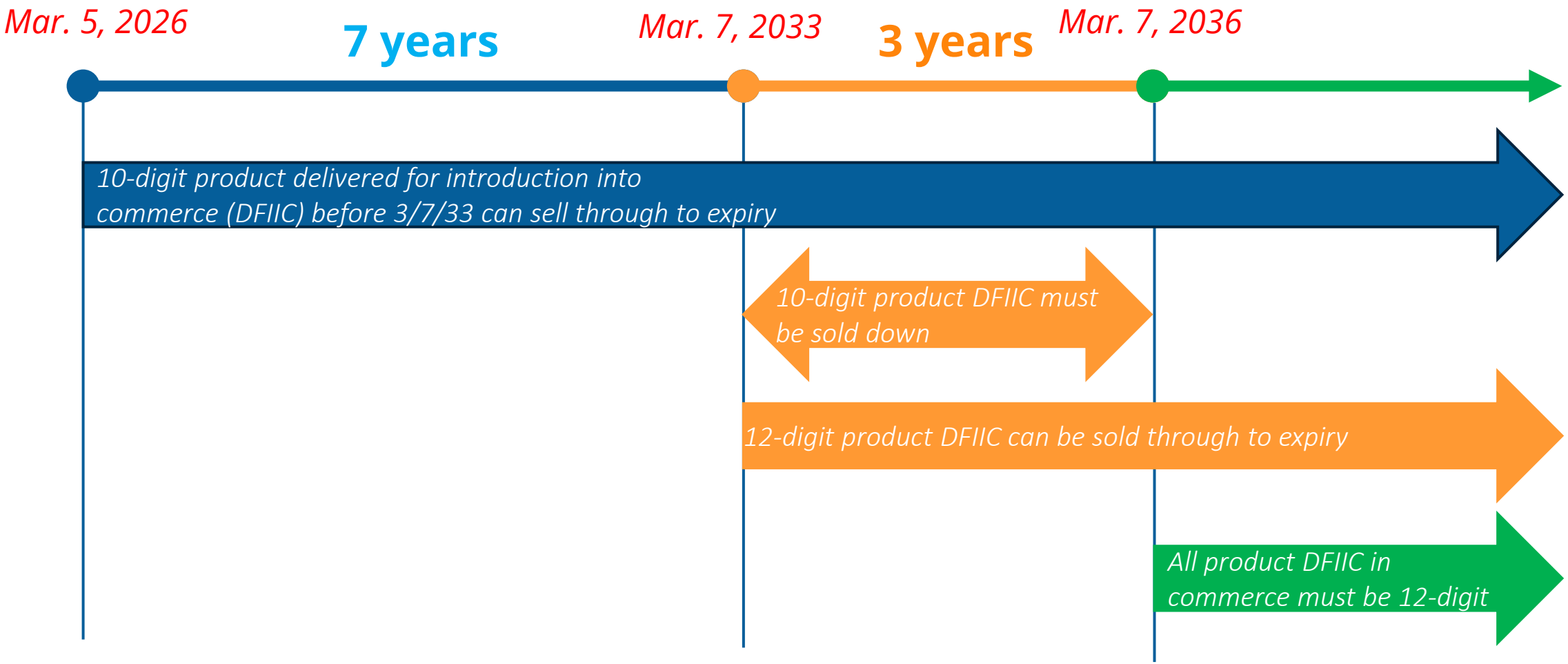
GTIN (01) 00314141999995
EXP 2021-12-31
Batch/Lot (10) 987654321GFEDCBA
Serial (21) 100000000234
NDC (715) 014141-0999-99

Image Credit: GS1 US

Transition Timeline



Transition Product



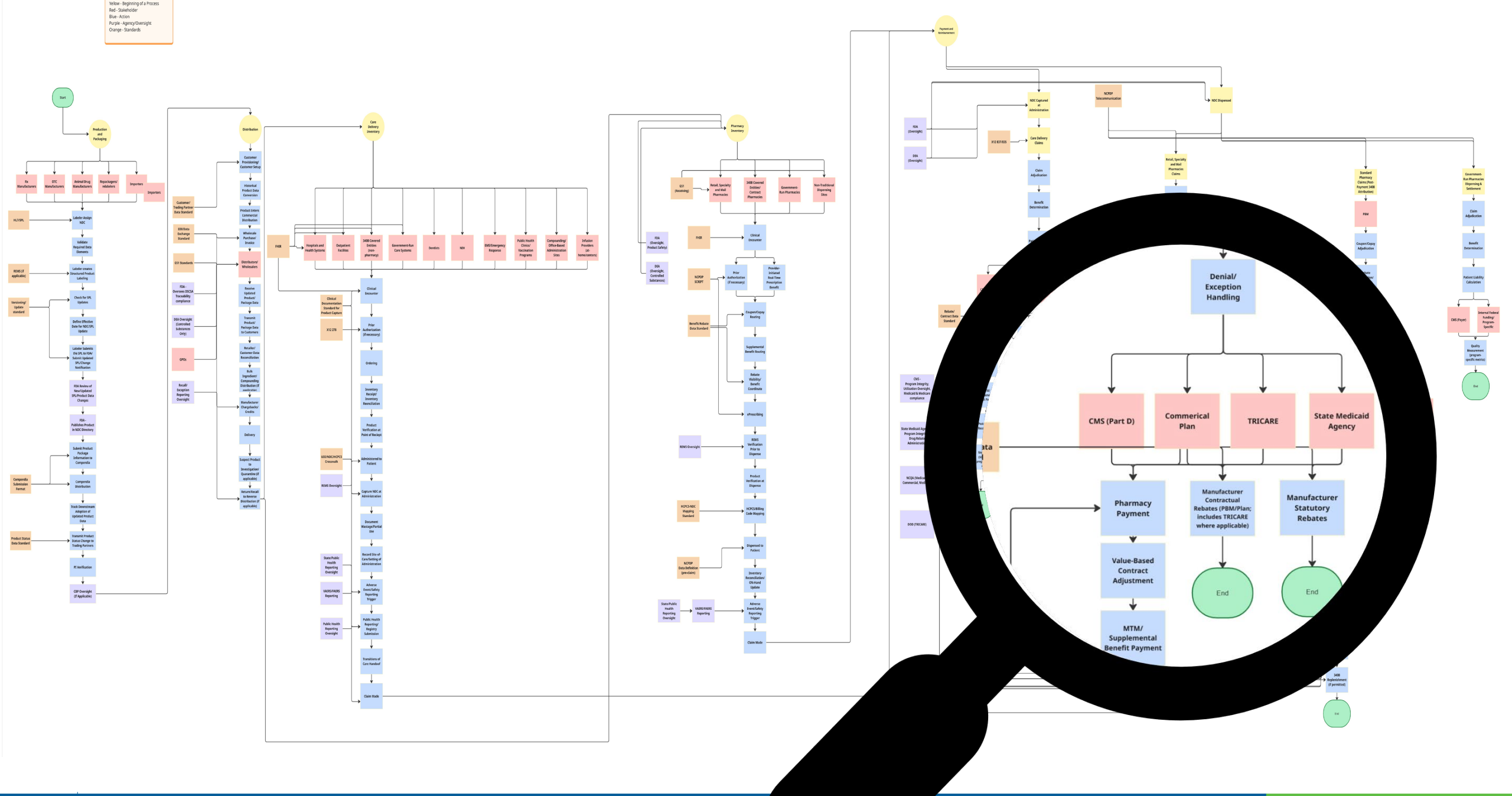
IMPACT

Knowns

- Most systems do not currently accommodate 12-digit NDCs
- Need to manage 10-, 11-, and 12-digit NDCs simultaneously
- One uniform format (6-4-2) post transition
- How current formats will crosswalk to new format
- NDC and GTIN will be decoupled
- Linear barcodes will change or be removed

Unknowns

- Duration of the 10-digit tail
- What will replace the UPC-A
- How historical data will be managed
- When/how HIPAA and dozens of other regs will be updated
- Whether physical product and associated data will utilize the same format
- How we get there



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1. The breadth of impact and interdependency is immense.

2. A successful timeline is front-loaded, and there are some major dependencies that hit very early in the process.

3. The physical and digital ecosystems are connected but have distinct needs and challenges.

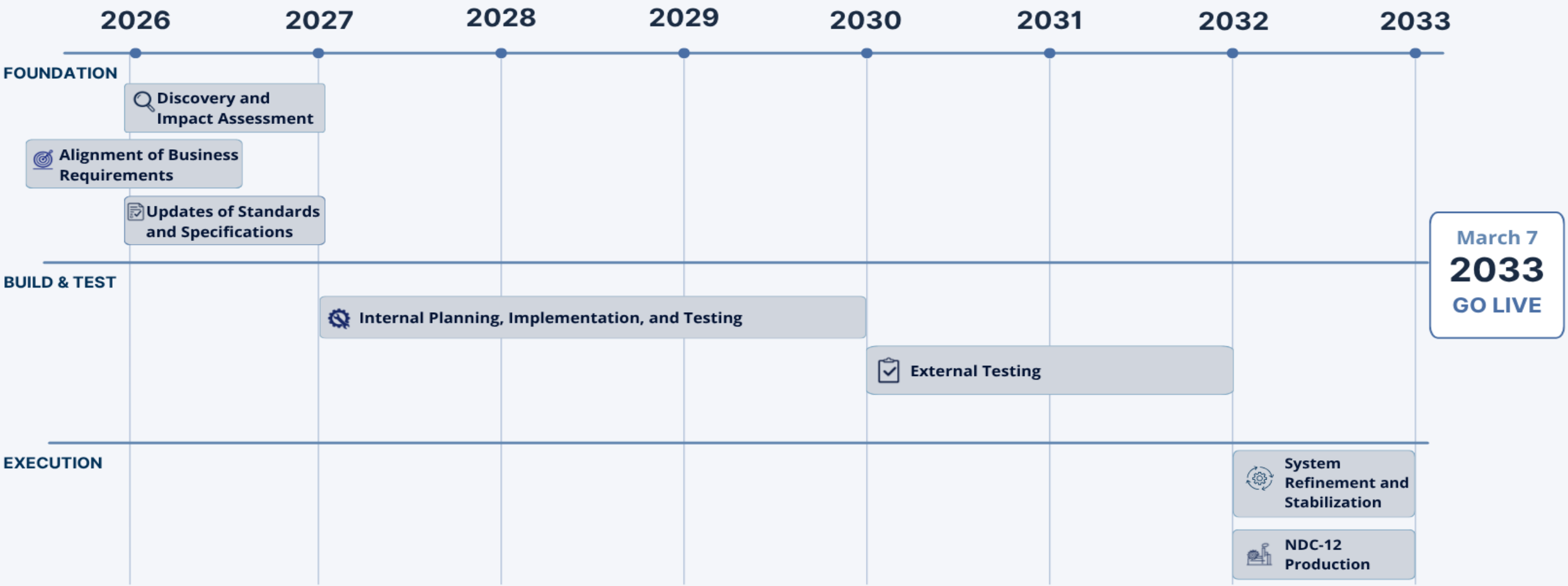
4. Dual-operability is the defining challenge.

5. The barcoding rule is both a complexity and major strategic opportunity.

6. Continued collaboration and cross-sector visibility is critical to success.

PLANNING

Ecosystem-Wide Timeline



Follow the Identifier

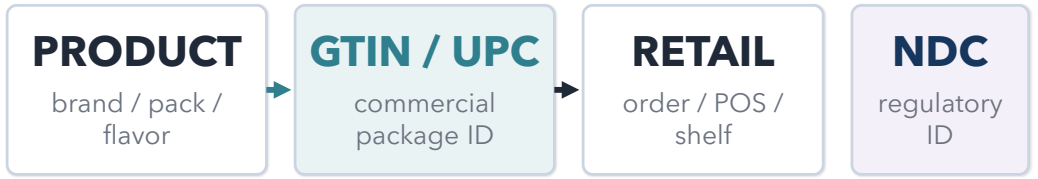
The same FDA change creates very different operational risk depending on where NDC sits in the product architecture.

RX — NDC often tightly coupled to commercial

12-digit NDC exposes legacy coupling / derification logic

IDENTITY ARCHITECTURE

OTC — GTIN / UPC often already separates commerce from regulation



NDC maintained as a separate regulatory attribute

COMMERCIAL FLOW

1 Rx: Architecture Risk

Find every place where NDC is embedded, derived, or assumed to be the product key.

2 OTC: Mapping Risk

Validate NDC ↔ GTIN ↔ SKU relationships and keep regulatory data separate from commercial identity.

3 Channel: Coexistence Risk

Distributors and pharmacies need clean crosswalks through the 10 → 12-digit transition.

TAKEAWAY **The question is not "Where is the NDC?" – it is "What systems treat the NDC as the identity of the product?"**

5 Steps to Readiness

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1 FIND IT

Map the landscape

- Identify every place identity is created, transformed, exchanged, or consumed
- Identify internal and external dependencies
- Prioritize high-risk systems & dependencies

2 SEPARATE IT

Define the relationship

- Distinguish NDC from GTIN and other identifiers
- Stop relying on structural inference

3 REDESIGN IT

Build the target state

- Update product master & identifier architecture
- Remediate ERP, regulatory, labeling and interfaces
- Design explicit NDC-GTIN mappings

4 TRANSITION IT

Manage coexistence

- Prepare to support 10- and 12-digit NDCs during transition
- Coordinate product and system updates
- Sequence changes to avoid product identity breaks

5 PROVE IT

Validate the ecosystem

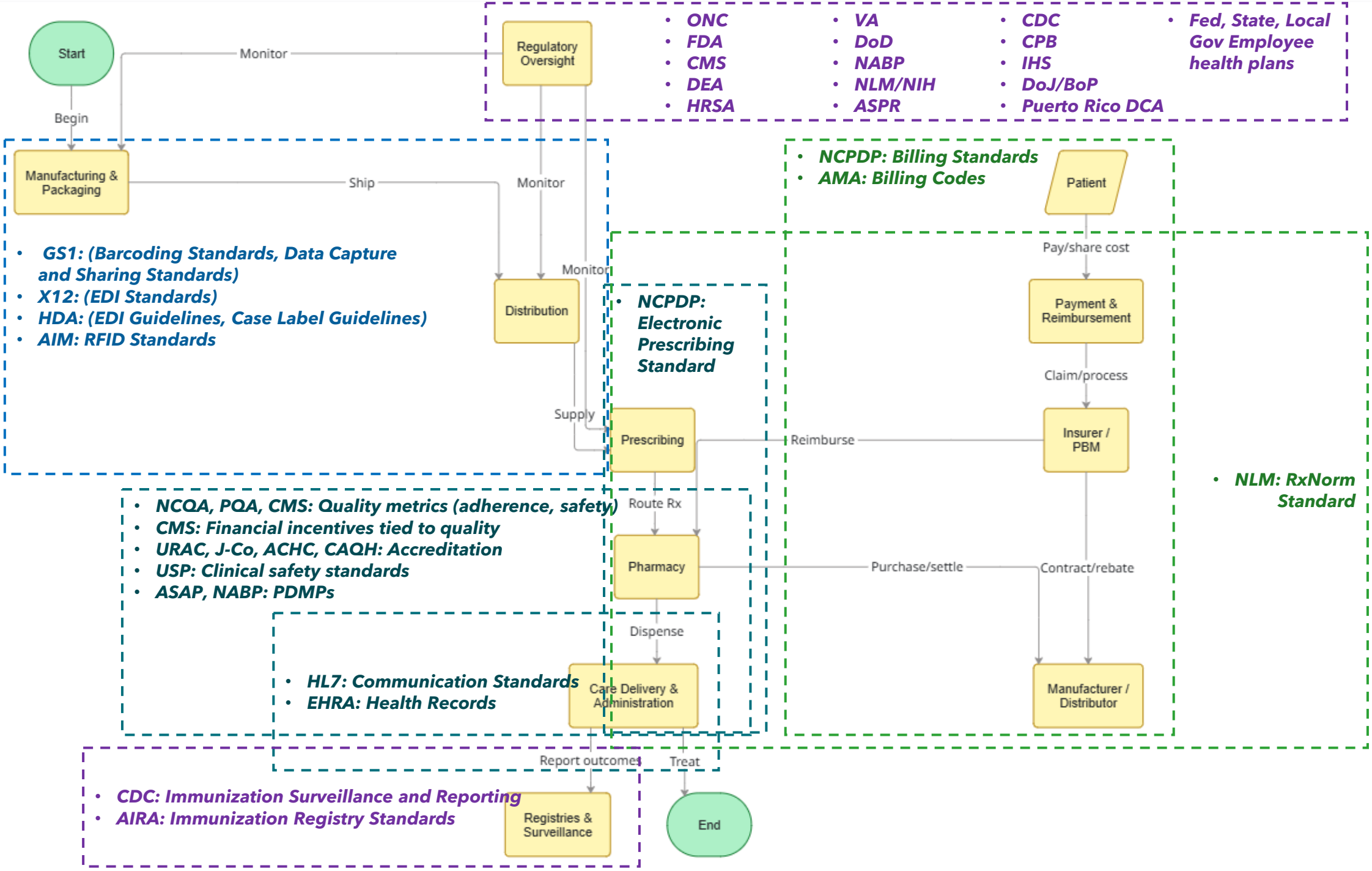
- Internal test of systems and connections
- End-to-end external testing to ensure the NDC flows throughout

Governance Principle Centralize the identifier/data architecture. Decentralize execution into accountable business workstreams.

Treat this as an enterprise program, not an IT project.

EXECUTIVE SPONSOR	PROGRAM LEAD	WORKSTREAM LEADS	PARTNER FORUM
Enterprise accountability	Integrated roadmap & decisions	Regulatory • Data • IT • Quality • Packaging • Finance • Supply Chain	Distributors • Pharmacies • Vendors

NDC Format Change: Who's on First?



NEXT STEPS

Socialize it

Budget it

Identify a lead and assemble a team

Get involved and stay current

The NDC Coordination & Implementation Forum

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A cross-sector coordination body designed to ensure the entire ecosystem moves forward with shared insight, aligned priorities, and coordinated execution.

Accelerates Cross-Sector Learning

Creates a structured mechanism to share real-world challenges, surface emerging risks early, and translate lessons from one sector into action for others.

Aligns the Ecosystem Across Independent Efforts

Connects and amplifies the work of GS1, NCPDP, HDA, H17, and others, identifying gaps, overlaps, and dependencies to ensure a coherent, system-wide plan.

Serves as a Central Industry-Government Interface

Provides a trusted forum for dialogue with FDA, CMS, OMC, NIH, CDC, states, and other agencies, enabling real-time feedback loops on implementation challenges and surfacing areas where regulatory clarity or flexibility is needed.

Drives Rapid Alignment on Cross-Sector Issues

Establishes time-bound "strike forces" to resolve priority challenges, including HIPAA alignment, testing models, and barcode strategy.

Coordinates Testing and Piloting Across the Ecosystem

Aligns stakeholders around shared testing approaches and timelines, ensuring cross-sector readiness ahead of the critical 2030–2032 testing window.

Consolidates Education, Guidance, and Resources

Creates a single access point for implementation materials, aligns messaging, and reduces duplication and confusion across the ecosystem.

Why Stakeholders Are Joining

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- Early visibility into risks across other sectors
- Ability to shape how key issues are resolved
- Direct engagement with FDA, CMS, and other agencies
- Reduced cost through aligned implementation
- Keeps your organization synchronized with ecosystem progress

Join the Conversation. Shape the Transition.

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Organizational Membership

Annual Membership

$5,000

per organization

- Unlimited participants from your organization
- Access to all quarterly forums, strike forces, and other events
- Full access to tools, outputs, and shared resources

Per-Participant Access

Attend quarterly forums on a per-person basis, ideal for organizations exploring participation before committing to full membership.

Virtual Quarterly Forums

$399

per person

In-Person Forums

TBD

per person

Strike force participation available to organizational members only

Membership and signup at *www.NDCForum.org*

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Join the Conversation. Shape the Transition.

Q3 QUARTERLY FORUM

WEDNESDAY
SEPTEMBER 23, 2026

1:00 – 3:00 PM ET
VIRTUAL

KICKOFF FORUM – FREE TO ATTEND!
Initial implementation roadmap, ecosystem updates, key risks & dependencies, and more.

Q4 QUARTERLY FORUM

TUESDAY
DECEMBER 8, 2026

1:00 – 3:00 PM ET
VIRTUAL

WEDNESDAY
DECEMBER 9, 2026

1:00 – 3:00 PM ET
VIRTUAL

CONTINUE THE MOMENTUM.
New updates, progress on strike force initiatives, testing & piloting insights, and what's ahead.

Learn more and register at www.ndcforum.org/ndcquarterlyforums

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The NDC Coordination and Implementation Forum is the healthcare ecosystem's coordinating hub for the 12-digit NDC transition, enabling stakeholders to share insights, align priorities, and drive coordinated execution across health care.

www.NDCforum.org