Revising the National Drug Code Format and Drug Label Barcode Requirements

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What is Changing?

- FDA is standardizing the National Drug Code (NDC) to a uniform 12-digit format
- Current system: 10-digit NDCs in multiple configurations (4-4-2, 5-3-2, 5-4-1)
- New system: All NDCs will be 12 digits in 6-4-2 format
  - 6-digit labeler code
  - 4-digit product code
  - 2-digit package code

How NDCs Will Convert?

Conversion Method:

- Add leading zeros to appropriate segments
- Creates uniform 6-4-2 format

Examples:

- 9999-0123-45 (4-4-2) → 009999-0123-45 (6-4-2)
- 99999-123-45 (5-3-2) → 099999-0123-45 (6-4-2)
- 99999-1234-5 (5-4-1) → 099999-1234-05 (6-4-2)

Why This Change is Necessary?

Challenges:

- FDA will run out of 5-digit labeler codes in 8-10 years
  - Under the previous regulation, FDA would have started assigning 6-digit labeler codes creating 2 additional formats
- Incompatible with HIPAA's 11-digit standard format
- Incompatible with linear barcode

The Solution:

- One standardized format for all stakeholders
- Eliminates need for format conversions
- Future-proof: 900-year supply* of labeler codes

When Will the Change Happen?

Key Dates:

- **Final Rule Publication Date:** March 5, 2026
- **Effective Date:** March 7, 2033 (7 years after publication in Federal Register)
- **Transition Period:** 3 years following effective date

What Must Happen When

During 7-Year Preparation Period:

- Plan for system updates to handle 12-digit NDCs
- Prepare new labeling and packaging designs and manage labeling production prior to effective date
- Coordinate with suppliers and distributors
- Train staff on new format

What Must Happen When

On Effective Date:

- FDA automatically converts all existing NDCs to 12-digit format
- FDA starts assigning 6-digit labeler codes
- Industry begins using 12-digit NDCs on new printed product labeling

During 3-Year Transition:

- FDA will maintain a conversion list of 10 and 12-digit formats
- Deplete existing 10-digit labeled inventory
- Transition to 12-digit labels as soon as feasible, and update listing SPLs (label)
- Both formats acceptable during this period only

Implementation Timeline – Key Dates

Final Rule Publication
March 5, 2026

Effective Date
March 7, 2033

Transition Period
March 7, 2033 - March 7, 2036

Total Implementation Window: 10 Years

Years 1–7 Preparation Period

- Readiness Planning
- System Updates & Training
- Labeling & Packaging Design



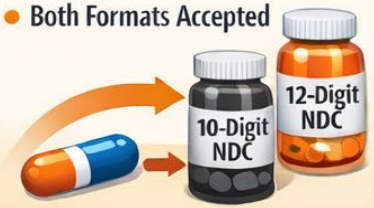
Effective Date March 7, 2033

- FDA Begins Issuing 12-Digit NDCs
- 12-Digit Labeled Products Enter Market



Years 8–10 Transition Period

- Deplete 10-Digit Inventory
- Transition to 12-Digit NDCs
- Both Formats Accepted



After Year 10

Only 12-Digit NDCs Permitted



Preparation Period Years 1–7 → **Transition Period** Years 8–10 → **After Year 10**

Labeling Requirements

When to Update Labels:

- Plan and prepare label updates before effective date
- Update as soon as possible after effective date
- No later than when existing labeling stock is depleted

Enforcement

- Products introduced into commerce BEFORE effective date: can remain on market until expiration
- Products introduced AFTER effective date with 10-digit NDCs and remain on market: subject to enforcement action after the 3-year transition period
  - With proper planning, most products should expire off the market

Barcode Requirements Update

Current Requirement:

- Linear barcode only (UPC-A format)
- EAN/UCC (a.k.a., GS1/GS1 US) or HIBCC standards

New Flexibility:

- Linear OR nonlinear barcodes permitted
- Must conform to widely recognized international standards
- FDA Center Director must recognize the format

Key Change:

- UPC-A cannot accommodate the new format
- GS1's new Application Identifier enables 12-digit NDC encoding in 2D DataMatrix



Who is Affected?

Primary Stakeholders:

- Drug manufacturers and repackagers
- Wholesale distributors
- Pharmacies (retail and hospital)
- Healthcare providers
- Insurance companies and PBMs
- Health IT vendors
- Government agencies (Medicaid, Medicare)

Scope:

- Approximately 740,000 listed drug packages

Drug Listings

Automatic Conversion:

- FDA will update all existing drug listing files on effective date
- No need to resubmit files solely for NDC format change
- Both 10-digit and 12-digit formats published during transition

Ongoing Requirements:

- All new listings after effective date must use 12-digit format
- Updates to existing listings must use 12-digit format
- Labeling changes including the new NDC format and barcode must be submitted in following June or December after the change
- FDA will maintain mapping database (at least through transition period)

DSCSA Considerations

Product Identifier Impact:

- 12-digit NDC incompatible with current GTIN-12/GTIN-14
- GS1's new application identifier enables NDC encoding in 2D DataMatrix
- Single barcode can satisfy both §201.25 and DSCSA requirements

Transaction Information:

- Must include 12-digit NDC after effective date
- Coordinate with trading partners during preparation period

Compatibility:

- Camera-based scanners required for 2D barcodes
- Plan equipment upgrades during 7-year preparation period

Benefits of Standardization

Patient Safety:

- Reduced medication errors from format confusion
- Elimination of conversion-related mistakes
- Clearer product identification throughout supply chain

Operational Efficiency:

- Single format eliminates multiple quality control steps
- Streamlined billing and reimbursement processes
- Reduced audit complexity
- Better inventory management

Long-term Cost Savings:

- No perpetual conversion costs
- Simplified software maintenance
- Reduced training requirements

Why Not Alphanumeric Codes?

FDA Considered But Rejected:

- 5-character alphanumeric labeler codes (e.g., A1B2C)
- Would provide 26+ million codes

Reasons for Rejection:

- **Safety Concerns:** Letters easily confused with numbers (O/0, I/1, S/5, G/6)
- **Cognitive Load:** 50 possible characters vs. 10 digits increases error risk
- **System Compatibility:** Many systems cannot handle alpha characters
- **Barcode Limitations:** Cannot compress alpha characters; incompatible with some scanners
- **Global Standards:** Not compatible with international supply systems
- **No Uniform Format:** Would still have multiple configurations

Affected Groups Coordination

FDA Outreach Plans:

- Work with industry associations
- Engage federal and state agencies
- Coordinate with HIPAA standard-setters
- Communicate with software vendors
- Update guidance documents

Industry Responsibilities:

- Update internal systems and processes
- Coordinate with supply chain partners
- Train personnel
- Test new systems thoroughly
- Plan for contingencies

Key Takeaways

Remember:

- **One Format:** 12 digits, 6-4-2 configuration for all NDCs
- **"Long" Timeline:** 7 years to prepare + 3 years transition = 10 years total
- **Automatic Conversion:** FDA converts existing NDCs; add leading zeros and maintain a roadmap for 3 years
- **Barcode Flexibility:** Linear or nonlinear formats now permitted
- **Plan Now:** Use preparation period to update systems and coordinate changes
- **No Extensions:** Effective date will not be delayed

Next Steps

- Review full final rule in Federal Register
- Assess your organization's systems and processes
- Develop implementation plan and timeline
- Budget for necessary updates
- Coordinate with trading partners
- Monitor FDA communications and guidance

Resources

- FDA NDC Format website: www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/national-drug-code-format
- FDA NDC Directory: www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory
- Regulations.gov Docket: FDA-2021-N-1351
- Contact: edrls@fda.hhs.gov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Common Questions Addressed

Q: Is the converted NDC a "new" NDC? A: No. It's the same NDC in a different format. No impact on pricing, rebates, or user fees.

Q: What about historical records? A: No requirement to update historical patient records or claims.

Q: Can we start converting labels before the effective date? A: Prepare designs, but don't use 12-digit labels until effective date.

Q: What if we can't finish by end of transition period? A: No extensions planned. Products with 10-digit NDCs introduced after effective date and remaining after transition period subject to enforcement.

Q: Will the effective date be extended? A: No. The 7-year delay is carefully calculated to occur before 5-digit codes are exhausted.