INSULIN ACTION PLAN

A TRANSPARENCY AND ACCOUNTABILITY FRAMEWORK FOR RAPID MARKET RELIEF

Executive Summary

This framework ensures the President's Executive Order translates into real results for American families—not studies, not task forces, but insulin on pharmacy shelves. Every action has a deadline. Every deadline is public. Delays will be visible and explained. Success will be measured by patient access and market competition, not by process completion.

SECTION A: IMPLEMENTATION AND COORDINATION

1. HHS-FDA Rapid Execution Directive

Establishes immediate operational roles, authorities, and deadlines to ensure FDA and HHS execute all EO actions without procedural delay.

Key Provisions:

- Command-level directive emphasizing speed, accountability, and interagency synchronization
- **Red Line Accountability Rule with Escalation:**
    - **5 business days:** Any delay exceeding 5 business days beyond an EO deadline must be escalated directly to the Implementation Coordinator with written justification identifying the blocking official, unit, or process
    - **10 business days:** Automatic Tier-2 escalation to Deputy Secretary/Commissioner level AND notification to White House Domestic Policy Council, with public posting on Milestone Tracker showing: delay reason, corrective action, and revised ETA
- Agencies shall not cite "ongoing review," "stakeholder consultation," or "internal coordination" as sufficient reasons for delay without specific, documented legal or safety constraints

Clock Management Rules:

- **What pauses the review clock ("clock-stops"):**
    - Manufacturer's written request for additional time
    - Request for Additional Information (RAI) issued by FDA (clock restarts upon manufacturer's complete response)

    - Discovery of material safety concerns requiring investigation
    - Required consultation with external advisory committee
- **What does NOT pause the review clock:**
    - Internal FDA coordination or clearances
    - "Awaiting signature" or "pending approval"
    - Staff unavailability or resource constraints
    - "Under legal review" without specific citation
    - Translation or formatting issues
- **Clock-Stop Documentation:** Any clock-stop exceeding 3 business days must be accompanied by written justification approved by both the Review Team Lead and the Implementation Coordinator, and published on the Public Milestone Tracker within 24 hours

Expedited Clearance Protocol:

All internal clearances (legal, communications, Paperwork Reduction Act compliance) shall operate under a **48-hour turnaround requirement**. Any office requiring more than 48 hours must provide:

- Written legal citation necessitating additional time, OR
- Specific safety rationale requiring extended review

Unresolved clearance delays exceeding 48 hours escalate automatically to the Implementation Coordinator for resolution.

Status: Draft and release concurrently with FDA guidance (by Day 30)

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2. FDA Interim Guidance: Reliance for FDA-Verified Insulin Access

Provides clear, public instructions for manufacturers submitting insulin products already approved by trusted foreign regulators (EMA, MHRA, PMDA).

Purpose: Operationalize reliance on preexisting international reviews under current statutory authority (42 U.S.C. § 262(k); 21 U.S.C. §§ 356c, 393, 374).

Content:

- Model dossier outline (maximum 10 pages)
- **Definition of Complete Application** appendix specifying all required elements
- Required documentation checklist
- Review process and Service Level Commitments (SLCs)
- Acceptance criteria for foreign assessments
- Post-market surveillance requirements
- Clock management rules and clock-stop criteria

Service Level Commitment (SLC):

- 10-15 business days for complete applications

- If missed: FDA must publish variance memo within 48 hours explaining delay, corrective actions, and revised completion date
- Variance memo triggers corrective action review by Commissioner

Completeness Determination:

- FDA must issue completeness determination within 5 business days of submission
- Failure to issue determination within 5 days = application deemed complete for timeline purposes
- Silence cannot toll the clock

Status: Day 30 deliverable per EO Section 2(b)

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3. Interagency Bottleneck Elimination Protocol

Defines real-time coordination and escalation channels among FDA, CMS, and HHS to identify and remove administrative bottlenecks immediately.

Purpose: Replace slow consensus processes with fast resolution mechanisms.

Mechanisms:

- **Daily coordination calls** during first 60 days (transition to weekly after Day 60)
- Designated point persons with decision-making authority at each agency
- **48-hour maximum turnaround** for interagency approvals
- Direct escalation to Implementation Coordinator for unresolved disputes
- **Expedited Clearance Protocol** applies to all interagency dependencies:
    - Legal clearances: 48-hour turnaround
    - Communications clearances: 48-hour turnaround
    - OMB/PRA clearances: 48-hour turnaround or written justification

Clearance Bypass Authority:

The Implementation Coordinator may authorize provisional action pending clearance completion when:

- A deadline is at imminent risk (within 3 business days)
- The clearance office has exceeded 48 hours without specific legal citation for delay
- No concrete safety or legal concern has been articulated

Provisional actions remain subject to subsequent modification if clearance identifies legitimate concerns.

Status: Implemented within 15 days and maintained through completion of EO milestones

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4. Competitive Neutrality and Statutory Compliance Analysis

A comprehensive legal memorandum documenting statutory authority and ensuring competitive neutrality for all qualifying manufacturers—domestic or foreign.

Purpose:

- Provide DOJ and HHS General Counsel with defensible legal framework
- Demonstrate EO alignment with existing statutory authority (42 U.S.C. § 262(k), 21 U.S.C. § 356c)
- Ensure fair competition without favoritism
- Establish litigation readiness

Litigation and Records Discipline:

- **Rapid-response litigation cell** (HHS/DOJ/OGC) stands ready to defend Order
- **Same-day posting requirement:** All final guidance, FAQs, metrics, and non-privileged delay memos posted publicly on finalization date
- **FOIA preemption:** Proactive disclosure prevents "document unavailable" slow-rolls
- **Records preservation:** All delay justifications, variance memos, and escalation documents preserved for potential litigation

Public Transparency Component:

An executive summary of this analysis shall be published within 30 days at HHS.gov, demonstrating that the streamlined pathway is available to any manufacturer—domestic or foreign—meeting objective safety and quality criteria, ensuring fair competition without favoritism.

Status: Internal analysis completed within 15 days; public executive summary published by Day 30

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5. Implementation Progress Tracker

Centralized digital system managed by HHS to monitor EO milestones in real time with weekly internal updates to the White House Domestic Policy Council.

Components:

- Application intake and processing metrics
- Deadline compliance tracking with clock-stop visibility
- Obstacle identification and resolution status
- **Resource allocation and staffing levels** (BsUFA-funded positions, detailees, vacancies)
- Service Level Commitment adherence rates
- Variance memo tracking
- Escalation history and resolution times

BsUFA Resourcing and Hiring Flexibility:

- Commissioner authorized to temporarily reallocate BsUFA-funded staff to insulin review team
- Authority to accept surge detailees from other FDA divisions
- **Monthly staffing reports** showing:
    - Current FTEs assigned to insulin review team
    - Number of detailees supporting the initiative
    - Vacancies and recruitment status
    - Staff utilization rates

Staffing levels published on Public Milestone Tracker and updated monthly.

Public Summary: Available by Day 30 at HHS.gov

SECTION B: TRANSPARENCY AND MARKET IMPACT

6. Insulin Price Transparency Dashboard

A public, data-driven platform showing quarterly insulin price comparisons across the U.S. and allied nations (UK, Germany, France, Japan, Canada).

Features:

- Side-by-side price comparisons by product
- Median international reference prices
- Price trend analysis over time
- Machine-readable data downloads (JSON, CSV)
- Accessible charts and visualizations

Goal: Empower patients, policymakers, and markets with verified price data.

Status: Launch by Day 30 per EO Section 3(a)

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7. Public Milestone Tracker (HHS.gov)

Displays agency progress toward every EO deadline, updated continuously in real time.

Information Displayed:

- Each EO deadline and responsible agency
- Current status (on track / at risk / delayed / completed)
- For delays: specific reason and revised timeline
- Weekly application metrics
- Links to all published guidance and tools
- **Enhanced visibility requirements:**
    - **Staffing levels** for insulin review team (updated monthly)

    - **Clock-stops:** All review pauses >3 days with justification and approval chain
    - **Variance memos:** Published within 48 hours of any missed SLC
    - **Escalation history:** Tier-1 and Tier-2 escalations with resolution status

Purpose: Convert transparency into enforcement—public accountability against delay.

URL: HHS.gov/InsulinAction

Status: Launch by Day 30 per EO Section 5(c)

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8. Patient and Provider Resource Toolkit

Comprehensive suite of tools enabling immediate action once new insulin products enter the market.

Components:

- **Cash-Price Pharmacy Locator:** Interactive map showing which pharmacies stock newly available FDA-verified insulin products, with real-time pricing
- **Plain-Language Patient Guides:** Product options, how to switch safely, adverse event reporting, financial assistance resources
- **Provider One-Pagers:** Product mapping, dose equivalence tables, switching protocols, counseling scripts
- **Pharmacist Reference Materials:**
    - Substitution guidelines with state law summaries
    - DSCSA verification procedures for streamlined pathway products
    - Cold-chain integrity protocols and documentation requirements
    - **Professional practice clarification document** explaining that pharmacists following state law and DSCSA requirements when dispensing FDA-verified insulin are exercising appropriate professional judgment
    - Insurance coordination tips and prior authorization templates
    - Liability FAQ addressing common professional concerns
- **Public Education and Safety FAQ:** Clear answers about EMA/MHRA/PMDA, post-market surveillance, product switching, adverse event reporting

Status: Day 45 deliverable per EO Section 3(b)

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9. Market Impact Indicators Dashboard

Within 90 days, HHS shall publish a Market Impact Dashboard tracking measurable outcomes:

Metrics Tracked:

- Number of new insulin products entering U.S. market

- Number of participating manufacturers and applicants
- Average retail price changes in pilot markets vs. control markets
- Prescription abandonment rate trends
- Emergency department visits for diabetic ketoacidosis in pilot regions
- Geographic distribution of newly available products
- Patient out-of-pocket cost changes
- Service Level Commitment adherence rate (% of reviews completed within 10-15 days)
- Average actual review time for completed applications
- Clock-stop frequency and duration

Purpose: Provide objective, data-driven evidence of policy impact—positive or negative—to inform ongoing implementation and legislative recommendations.

Update Frequency: Monthly

Status: Launch by Day 90

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10. Reference Pricing Methodology Paper

Technical document explaining how international reference prices are calculated and maintained.

Content:

- Data sources and collection methodology
- Currency adjustment procedures
- Update frequency and timing
- Quality assurance processes
- Transparency safeguards

Purpose: Inform, not delay, implementation. Ensure methodological integrity.

Status: Published by Day 45 per Action Plan timeline

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11. Federal Facility and Payer Guidance

Encourages rapid adoption of lower-cost insulin products in federal healthcare systems and promotes fair formulary treatment in private insurance.

Federal Facilities:

- VA, IHS, DoD, and 340B program guidance
- Procurement procedures
- Formulary evaluation criteria
- Acquisition playbooks

Private Payers:

- Non-binding recommendations for tier parity
- Prior authorization streamlining
- Beneficiary communication best practices
- Voluntary "Participating Plans" recognition list

Status: Day 45 deliverable per EO Section 3(d) and 3(e)

SECTION C: STAKEHOLDER ENGAGEMENT AND LEGISLATIVE PATH

12. Stakeholder Engagement Plan

Coordinates proactive outreach to patient advocates, healthcare providers, pharmacists, state boards, and industry to ensure smooth rollout and accurate public communication.

Engagement Activities:

- Provider webinars and CME/CE programs
- Pharmacy association briefings
- Patient advocacy roundtables
- State pharmacy board coordination
- Manufacturer office hours
- Media and editorial board briefings

Timeline: Engagement begins immediately upon EO signature

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13. Bipartisan Implementation Advisory Group

Within 30 days, the Secretary shall convene a small advisory group (5-7 members) providing diverse perspectives on implementation.

Composition:

- Patient advocates from both progressive and conservative organizations
- Free-market healthcare economists
- Former FDA officials from multiple administrations
- Endocrinologists and primary care physicians
- Rural health representatives

Purpose:

- Provide real-time feedback on implementation

- Identify problems early
- Demonstrate broad ideological support
- Generate independent validation

Meeting Frequency: Monthly during first 6 months

Output: Brief quarterly public letters to the President on implementation progress, published at HHS.gov

Status: Convened by Day 30

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14. State Partnership Initiative

HHS and FDA shall establish a State Partnership Initiative, working directly with state pharmacy boards and Medicaid programs to harmonize implementation and share best practices.

Components:

- Direct coordination with state pharmacy boards
- Model state legislation for insulin interchangeability
- Technical assistance on implementation
- Best practice sharing across states
- Identification of "lighthouse states" demonstrating early success

Goal: Create 5-10 lighthouse states demonstrating successful implementation within 90 days, serving as replicable models for broader adoption.

State Benefits:

- Federal technical support
- Access to early data and lessons learned
- Recognition as innovation leaders
- Template materials and resources

Status: Launch within 30 days

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15. Early Impact Communications Strategy

HHS shall identify and publicize the first 10 patients who successfully access lower-cost insulin through the streamlined pathway.

Documentation:

- Previous monthly insulin costs vs. new costs
- Health outcomes and diabetes management improvements

- Geographic distribution showing broad access
- Patient testimonials (anonymized where requested)

Distribution:

- Case studies published at HHS.gov
- Media briefings and press releases
- Congressional testimony materials
- Patient advocacy organization partnerships

Purpose: Humanize the policy impact with real stories that resonate across the political spectrum.

Timeline: Begin documentation by Day 60; first stories published by Day 90

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16. Congressional and Public Briefing Packet

Comprehensive materials positioning the EO as proof-of-concept for lasting bipartisan reform.

Content:

- Market failure analysis: how duplicative regulation inflated prices
- Legal framework: statutory authorities supporting the EO
- Safety record: international regulatory equivalence evidence
- Fiscal impact: projected $4-5B annual federal savings
- Legislative pathway