

## Rapid Initiation to ART – Model Policy Elements

Element	Component	Best Practice
<b>Core</b>	<b>Program</b>	✓ Mandate Rapid Start program standards of care and outcome measures
	<b>Dedicated Staff</b>	✓ Create Rapid Start Director/Coordinator/Office of Rapid Start
	<b>Data Collection</b>	✓ Mandate data collection and reporting of Rapid Start metrics and outcomes
	<b>ADAP Enrollment</b>	✓ Mandate a presumptive ADAP enrollment policy and mechanism at state Health Department
	<b>Medication Support</b>	✓ Mandate dispensing of ART starter packs (30-day supply) to newly diagnosed HIV+ individuals under standing orders
	<b>Funding</b>	✓ Provide sufficient funding for programming staff capacity to ensure immediate engagement in HIV care for newly diagnosed HIV+ individuals
<b>Ancillary</b>	<b>Linkage to Care</b>	✓ Establish working relationships between HIV testing programs and Rapid Start clinical providers, including functional alter systems to prioritize those newly diagnosed
	<b>Clinical Guidance</b>	✓ Create a mechanism for training and offering clinical care and infectious disease specialty care providers on Rapid Start
	<b>Barrier Reduction</b>	✓ Prohibit cost-sharing (co-payments, co-insurance, deductibles), prior authorization, step therapy, or any other protocol that could restrict or delay dispensing of ARVs
	<b>Program Expansion</b>	✓ If piloting Rapid Start programs, implement strategies to expand standard of care to all funded HIV testing and care sites

## **DRAFT Model Legislation: Rapid Start HIV Treatment Act**

### **MODEL LEGISLATION**

#### **Section 1: Short Title.**

This Act shall be known as the “Rapid Start HIV Treatment Act of 202X.”

#### **Section 2: Findings.**

The [state legislature] finds that:

(a) Immediate initiation of antiretroviral therapy for newly diagnosed individuals with HIV has significant societal, public health, and personal health benefits, including, but not limited to:

- (i) **Reduction in Community Viral Load:** Rapid treatment lowers the overall community viral load, reducing the risk of HIV transmission at the population level.
- (ii) **Prevention of New Infections:** By decreasing viral load quickly, rapid ART initiation reduces the likelihood of transmission of HIV, thereby preventing new HIV infections and overall HIV incidence.
- (iii) **Cost-Effectiveness:** Early treatment reduces the long-term health care costs associated with HIV, including fewer hospitalizations and reduced need for more complex treatments.

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- (iv) **Enhanced Public Health Surveillance:** Rapid initiation helps integrate patients into the healthcare system sooner, improving data collection and monitoring of HIV trends and management efficacy.
- (v) **Reduction in Health Disparities:** Rapid initiation programs can be designed to reach underserved communities, helping to reduce health disparities related to HIV.
- (vi) **Improved Long-term Health Outcomes:** Individuals who start ART immediately after diagnosis have better long-term health outcomes, including lower rates of AIDS-related complications and other co-morbidities.
- (vii) **Reduced Risk of Transmission:** Rapid initiation of ART reduces an individual's viral load quickly, significantly decreasing the risk of transmitting the virus to others.
- (viii) **Preservation of Immune Function:** Starting ART promptly helps preserve immune system function and prevents irreversible damage caused by HIV.
- (ix) **Psychological Benefits:** Early treatment and associated supports can alleviate the stress, anxiety, and uncertainty associated with an HIV diagnosis, improving overall mental health and quality of life.
- (x) **Decreased Mortality:** Immediate ART is associated with reduced HIV-related mortality, as effective suppression of the HIV virus prevents the progression to AIDS.

(b) State programs to facilitate successful Rapid Start require an integrated approach involving healthcare providers, support staff, and robust funding mechanisms.

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### **Section 3: Definitions.**

For purposes of this Act, the following terms shall have the following meanings unless the context clearly requires otherwise:

“AIDS Drug Assistance Program” or “ADAP”, the state program established under the Ryan White HIV/AIDS Program (RWHAP) Part B to provide FDA-approved medications to treat income-eligible people with HIV.

“Antiretroviral therapy” or “ART”, any therapy approved for the treatment or prevention of HIV by the federal Food and Drug Administration, including any pre- or post-exposure prophylaxis drug.

“HIV”, human immunodeficiency virus.

“HIV prevention services”, any ancillary or support health service determined by the commissioner of public health that is necessary to: (1) ensure that any preexposure prophylaxis drug is prescribed or administered to a person who is HIV negative to prevent HIV transmission and has no medical contraindications to the use of such a drug; (2) ensure that any treatment and (2) monitor such a person to ensure the safe and effective ongoing use of such a drug through: (A) an office visit; (B) laboratory testing; (C) testing for a sexually transmitted infection; (D) medication self-management and adherence counseling; (E) or any other health service

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specified as part of comprehensive HIV prevention drug services by the United States Department of Health and Human Services, the United States Centers for Disease Control and Prevention or the United States Preventive Services Task Force.

“Presumptive ADAP enrollment”, immediate conditional enrollment in the state’s AIDS Drug Assistance Program (ADAP) based on self-attestation of income and residency eligibility, providing full coverage for a period of not less than 30 days.

“Rapid Start”, the standard of medical care that prioritizes the immediate initiation of ART for the treatment of HIV ideally within 72 hours of an HIV diagnosis and no more than 7 days of diagnosis to reduce HIV levels as quickly as possible. Individuals who have been previously prescribed ART and have not started their medication regimen or have experienced an interruption in adherence to their regimen shall be eligible to receive Rapid Start services and will be prioritized equivalently to newly diagnosed individuals.

“Rapid Start Office”, the office within the Department of Health established under section 5 to implement the purposes of this Act.

### **Section 4: State Rapid Start Office.**

There shall be a Rapid Start Office within the Department of Health to oversee the implementation and administration of Rapid Start programs in accordance with this Act. The Rapid Start Office shall be responsible for program development, contract

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management, training, evaluation, and annual reporting on program outcomes. The Rapid Start Office shall create mechanisms to train and offer ongoing clinical guidance to primary care and infectious disease specialty care providers on Rapid Start.

The Rapid Start Office shall, not less than annually, submit a comprehensive report detailing the relative success of Rapid Start programs (i.e. number of programs that are operational, number of patients enrolled to date, proportion of enrolled patients initiating ART within 7 days, identified challenges to program implementation and operation, proposed responses to challenges) to the [State Legislature] and make it available to the public.

### **Section 5: Presumptive AIDS Drug Assistance Program (ADAP) eligibility.**

(a) The Department of Health shall ensure that any individual who: (i) has evidence of HIV infection; and (ii) verbally attests to meeting income and residency requirements of the ADAP be presumptively eligible for ADAP. Such presumptive eligibility shall provide full ADAP coverage for a period of not less than 30 days with options for extension of this eligibility period. For the purposes of this section, a reactive FDA-approved HIV test or a clinical diagnosis shall constitute evidence of HIV infection.

### **Section 6: Rapid Start Programs; Establishment and Requirements.**

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(a) The Rapid Start Office shall establish and maintain Rapid Start programs at designated HIV testing and clinical care sites.

Rapid Start programs implement the standard of medical care that prioritizes the immediate initiation of ART for the treatment of HIV ideally within 72 hours of an HIV diagnosis and no more than 7 days of diagnosis to reduce HIV levels as quickly as possible.

Individuals who have been previously prescribed ART and have not started their medication regimen or have experienced an interruption in adherence to their regimen shall be eligible to receive Rapid Start services and will be prioritized equivalently to newly diagnosed individuals.

(b) Rapid Start programs shall provide:

- (i) Immediate access to extended clinical appointments;
- (ii) Prescribing and dispensing of a 30-day ART starter dose supply prior to the completion of viral genotyping and safety-lab testing; and,
- (iii) Comprehensive support services including health education, transportation, housing assistance, nutrition, and psychosocial supports.

(c) Rapid Start programs will ensure close communication and coordination with HIV testing programs to facilitate timely linkage to care.

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(d) Rapid Start programs must operate in a non-discriminatory manner, providing equitable access to all individuals regardless of race, ethnicity, gender identity, sexual orientation, mode of exposure to HIV, immigration status, or ability to pay.

### **Section 7: Data Collection and Reporting.**

Rapid Start programs shall collect detailed data on program enrolment, ART initiation timelines, demographic information of enrollees, and health outcomes and shall report such data to the Rapid Start Office in a form, manner, and frequency specified by said Office. At a minimum, such programs shall collect and report:

- (i) the number of individuals with evidence of newly diagnosed HIV infection referred to the Program;
- (ii) the number of offers of enrollment into the Rapid Start Program made to newly diagnosed HIV+ individuals;
- (iii) the number of newly diagnosed HIV+ individuals enrolled in the Rapid Start Program;
- (iv) the number of individuals who decline the Rapid Start Program and their reason(s) for not enrolling;
- (v) the length of time from first evidence of new HIV+ diagnosis to the initiation of ART for Program enrollees;
- (vi) the length of time from initiation of ART and achievement of undetectable viral load for Program enrollees;
- (vii) core demographic data on Rapid Start Program enrollees (race/ethnicity, age, sex, gender identity, sexual orientation, mode(s) of exposure to HIV , disability status, primary or preferred language, housing status, insurance status); and,



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- (viii) proportion of individuals belonging to demographic categories identified by local epidemiologic data to have challenges engaging and being retained in HIV care enrolled in the Rapid Start Program who achieve undetectable viral load within 3 months of diagnosis.

### **Section 8: Funding and Reimbursement.**

Rapid Start programs will be funded through state appropriations, federal grants, and other available healthcare funding sources. Reimbursement mechanisms shall be established to cover the full costs of ART, including during periods of presumptive ADAP eligibility, without patient cost-sharing or prior authorization delays.

### **Section 9: Reduction of Barriers to Rapid Start.**

(a) Notwithstanding any general or special law to the contrary, any policy, contract, or certificate of health insurance subject to [*state health insurance statutes*]that provides coverage for ART or HIV prevention services shall not require:

- (i) any cost-sharing, including co-payments or co-insurance, or any deductible; and

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(ii) prior authorization, step therapy or any other protocol that could restrict or delay the dispensing or provision of any ART or HIV prevention services.

(b) Notwithstanding any general or special law to the contrary, any policy, contract, or certificate of health insurance subject to *[state health insurance statutes]* shall ensure that the rate of payment for in-network providers of ART and HIV prevention services delivered via interactive audio-video technology and audio-only telephone shall be no less than the rate of payment for the same service delivered via in-person methods.

### **Section 10: Effective Date & Regulatory Authority.**

This Act shall take effect immediately upon passage and approval by the Governor. The department of health and the department of insurance shall adopt any written policies, procedures or regulations necessary to implement this Act.