Updates:
Vermont All-Payer Accountable Care Organization Model Agreement

Importation of Prescription Drugs

Health Reform Oversight Committee
Ena Backus, Director of Health Care Reform
Agency of Human Services
November 13, 2020

VERMONT
AGENCY OF HUMAN SERVICES

Vermont All-Payer Accountable Care Organization Model Agreement

VERMONT
AGENCY OF HUMAN SERVICES

What is the All-Payer Accountable Care Organization Model Agreement?

- Vermont is including all major health care payers (Medicare, Medicaid, and Commercial issuers) in a model to pay for health care based on quality and outcomes instead of on a fee-for-service basis.

- Vermont has an agreement with the federal government to allow for Medicare's participation in its statewide model.

- The federal government is tailoring an approach for Vermont but has been clear that Value Based Payment is a shared priority.

How do we gauge progress?

There are three performance domains in the Vermont All-Payer Accountable Care Organization Model Agreement

1. Scale Targets
2. Financial Targets
3. Quality and Outcomes Targets

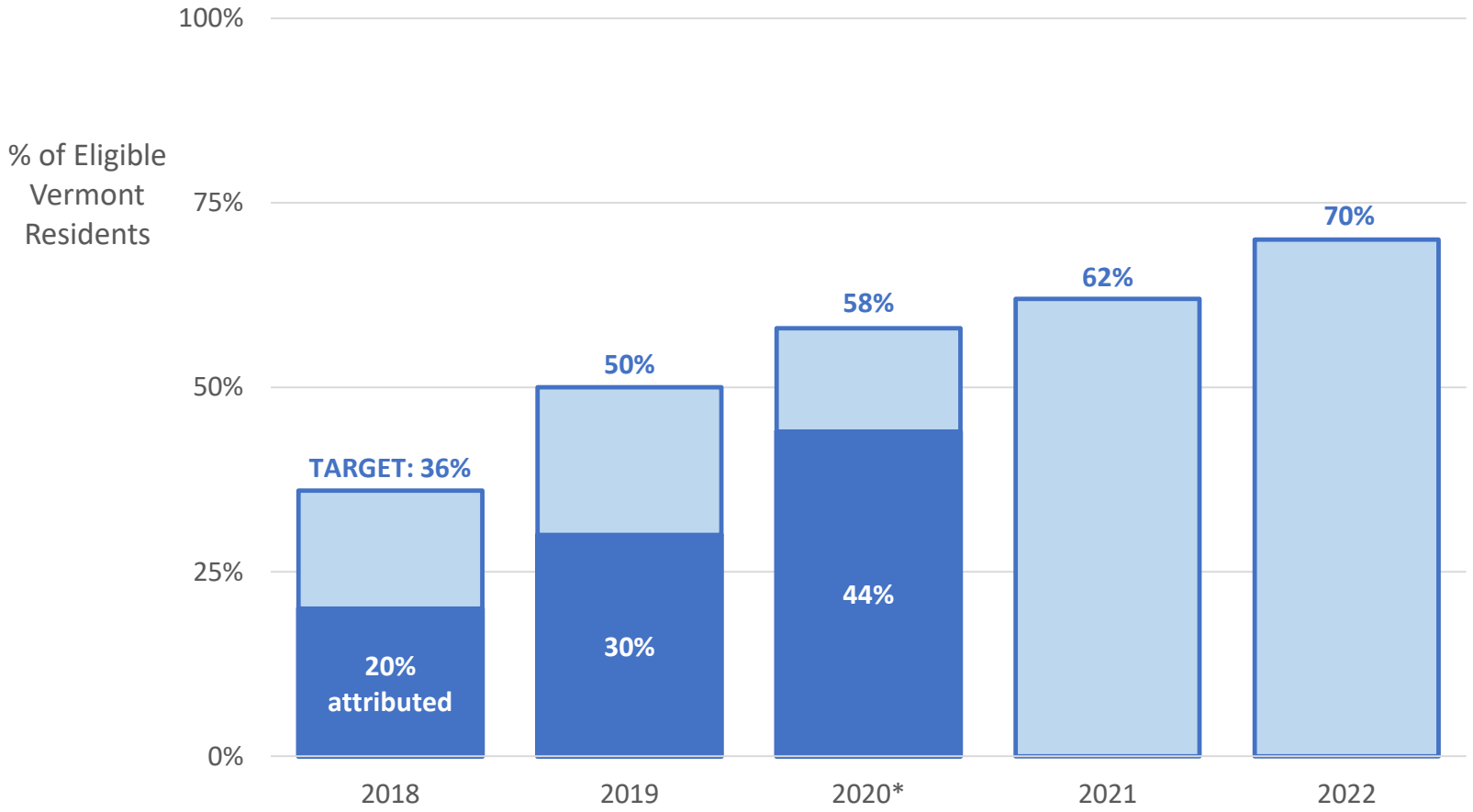
PERFORMANCE YEAR RESULTS
Performance Year 1 (2018)

Domain	Measure	Target	Result	On Target?
Scale	All-Payer Scale	36%	22%	No
	Medicare Scale	60%	35%	No
Financial	All-Payer TCOC Growth	4.3%	4.1%	Yes
	Medicare TCOC Growth	3.8%	0.8%	*Yes, but result is preliminary*
Health Outcomes and Quality of Care	Population-Level Health	Achieve 4 out of 6 outcomes	3 out of 6	No
	Health Care Delivery System Quality	Achieve 6 out of 9 outcomes	7 out of 9	Yes
	Process Milestones	Achieve 5 out of 7 outcomes	6 out of 7	Yes

VERMONT
AGENCY OF HUMAN SERVICES

RESULTS OVER TIME

All-Payer Scale

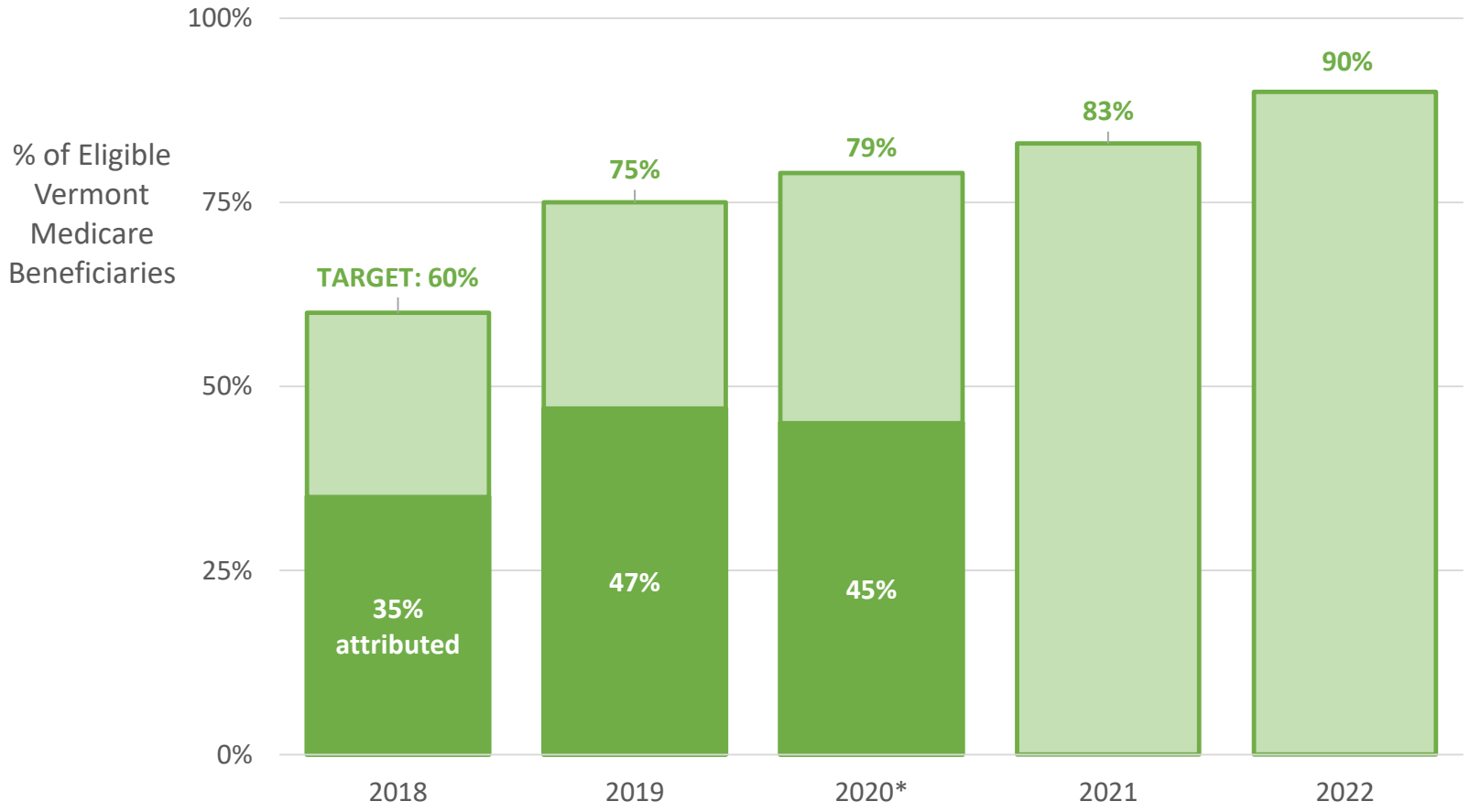


*Preliminary

VERMONT
AGENCY OF HUMAN SERVICES

RESULTS OVER TIME

Medicare Scale



*Preliminary

VERMONT
AGENCY OF HUMAN SERVICES

Continuous Improvement

"Moving to a system that pays providers for a population of patients, rather than for the individual services provided, would avoid the revenue shortage that providers are facing because of COVID-19. In fact, population-based payment models may provide a greater level of predictability for provider revenues in a way that could encourage longer term planning."

Dan Meuse, State Health and Value Strategies

- Vermont is committed to continuing the move away from fee-for-service reimbursement.

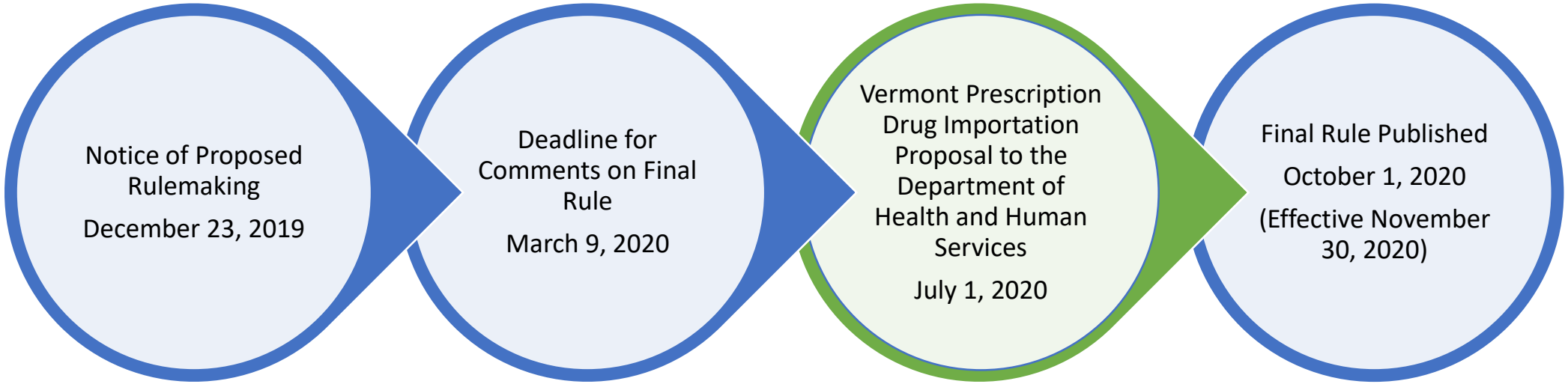
- To this end, four primary areas have been identified for improving Vermont's performance in the All-Payer ACO Model Agreement.

VERMONT
AGENCY OF HUMAN SERVICES

Importation of Prescription Drugs

VERMONT
AGENCY OF HUMAN SERVICES

Importation of Prescription Drugs: Food and Drug Administration Rule



VERMONT
AGENCY OF HUMAN SERVICES

Comments on Proposed Rule

- The Agency of Human Services (AHS) held three hearings to gather public input on Prescription Drug Importation on February 25, 2020.

- The State of Vermont submitted individual comments on the proposed rule on March 9, 2020 and participated in a group facilitated by the National Academy of State Health Policy which also commented on the proposed rule.

- Vermont reiterated its comments within its July 1, 2020 proposal to HHS.

Proposed Rule NASHIP Comment	Final Rule
State agency Section 804 Importation Program (SIP) Sponsors should not be limited to the state agency that regulates wholesale drug distribution and/or the practice of pharmacy in the state. Such a limitation would conflict with many state legislative mandates for SIPs and would be otherwise impractical.	A State agency that a State has authorized to submit a SIP Proposal may submit a SIP Proposal on behalf of the State, even if the State agency does not otherwise oversee pharmacists and wholesale distributors.
The final rule should allow FDA to conditionally approve SIPs that do not initially specify the Importer(s), Foreign Seller(s), relabeler(s), and repackager(s). The rule should allow the FDA to later fully approve the SIP when that information is provided. Potential SIP participants are unlikely to sign-on to participate in a SIP framework that has not been approved. The federal government should partner with the states in facilitating these arrangements, as appropriate. Docket No. FDA-2019-N-5711 8	FDA revised the rule to create a phased review process to review a SIP Proposal that does not identify a Foreign Seller in an initial submission but otherwise meets the requirements of this part. Importers, relabelers, and repackagers still need to be identified and the required information regarding these participating persons must be included in the initial submission of the SIP Proposal. A Foreign Seller must be identified within 6 months of the initial submission date of the SIP Proposal.
As written, the proposed rule would prohibit FDA approval of initial SIP Proposals that include multiple Foreign Sellers in Canada, both horizontally and vertically. Doing so will allow for more robust and effective SIPs. Not doing so, on the other hand, would allow drug manufacturers to discriminate against the one or few Foreign Seller(s) specified in SIPs, preventing SIPs from demonstrating to FDA that they can consistently and successfully import prescription drugs. The SIP would, essentially, be over before it began.	FDA revised the rule to clarify that each supply chain under a SIP must still be limited to one manufacturer, one Foreign Seller, and one Importer, but if the SIP can show that it has consistently imported eligible prescription drugs in accordance with section 804 of the FD&C Act and the rule, the SIP Sponsor can submit a supplemental proposal to add supply chains, which would each consist of one or more eligible prescription drugs, one Foreign Seller, and one Importer.