



COVID-19 Vaccine Program Provider Accountability and Waste Avoidance Policy

Providers perform vital functions within the COVID-19 Vaccination Program (Program) including properly storing, handling, and managing vaccine supply as well as administering vaccine to intended vaccine recipients efficiently.

The Georgia Immunization Program (GIP) for the Georgia Department of Public Health (DPH) has developed and implemented an Accountability and Waste Avoidance Policy (Policy) for Providers enrolled in the Program, documenting the requirements for continued Program enrollment, based on: the Provider Enrollment Agreement; DPH's COVID-19 Vaccine Plan, found at <https://dph.georgia.gov/document/document/georgia-covid-19-vaccine-plan/download>; applicable federal and state laws; and guidelines for vaccine management, including waste avoidance.

Program Violations

At the discretion of the Commissioner, DPH may assess penalties and/or require corrective action for the following:

- Administering COVID-19 vaccine to recipients outside of the current phase, as those phases are identified on DPH's website.
- Failing to monitor dose vaccine vials daily to track expiration.
- Failing to administer COVID-19 vaccine to a recipient to avoid waste as follows, with all steps documented:
 - If a vaccine dose is within one (1) hour of expiration and there are no scheduled appointments, contact locations that employ the current phase of eligible individuals per the state guidelines;
 - If no individuals in the current phase can be identified at these employment locations, contact the current phase of eligible individuals on the Provider's waitlist who can arrive within 30 minutes;
 - If no waitlist individuals can be identified, contact internal staff who have expressed interest in receiving a vaccine;
 - If unable to identify a recipient, administer to other individuals interested in receiving the vaccine regardless of phase eligibility; and
 - If no recipient can be identified, proceed with the waste instructions and recording.
- Administering COVID-19 vaccine to a vaccine recipient who is not a Georgia resident, unless said vaccine recipient claims to live or work in Georgia;
- Refusing to administer COVID-19 vaccine to a vaccine recipient who does not reside in the Provider's county;
- Selling or otherwise misdirecting COVID-19 vaccine;
- Billing a vaccine recipient or third party for COVID-19 vaccine, constituent products, or ancillary supplies;
- Billing a vaccine recipient for a COVID-19 administration fee not otherwise covered by insurance;
- Failing to preserve all records related to COVID-19 vaccine management for a minimum of three (3) years;
- Failing to enter into GRITS the required information within the required timeframes related to vaccine inventory, time of receipt of vaccine, doses administered, and vaccine waste;
- Failing to monitor and comply with COVID-19 vaccine expiration dates;
- Failing to monitor and comply with storage unit temperature requirements;

- Failing to use proper equipment to store and handle COVID-19 vaccine, including cold chain conditions and chain of custody at all times in accordance with the Emergency Use Authorization (EUA) or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit;
- Misrepresenting cold-chain capacity within the Provider's facility;
- Failing to provide vaccine recipients or caregivers the correct EUA Fact Sheet, a completed/updated vaccination records care, and v-safe information when the vaccine is administered;
- Failing to report adverse vaccine reactions to Vaccine Adverse Event Reporting System (VAERS);
- Ordering COVID-19 vaccine or reporting vaccine usage in quantities or patterns that do not match provider profile or otherwise involve over-ordering of COVID-19 vaccine doses;
- Waste of COVID-19 vaccine due to negligence, recklessness, or intentional actions; and/or
- Failing to comply with any other requirements of DPH or in the CDC COVID-19 Provider Agreement.

Penalties and Corrective Action

DPH may impose penalties as a result of and/or require Providers to take action to correct identified/detected abuse and/or waste if the abuse and/or waste is confirmed as a result of an investigation DPH/GIP conducts. The DPH/GIP Director or Deputy Director will review the investigative findings and make a recommendation on penalties and/or corrective action to the DPH Commissioner.

The penalties and/or corrective action may include:

- For Providers who vaccinate outside of Georgia's current phase as reflected on DPH's website, except as set forth in the Accountability and Waste Avoidance Policy to avoid wasting vaccine:
 - First Offense -- 45 day suspension from the Program and DPH will collect the Providers existing vaccine inventory within 72 hours for redistribution to enrolled Providers within the county. Sufficient inventory will be left with the suspended Provider for second dose vaccine recipient needs.

Note: The phased approach to vaccine rollout is managed by the State office of the Georgia Department of Public Health. All Providers in the state of Georgia must adhere to the plan as set by DPH. Inquires related to the phases shall be directed to the State DPH office DPH-COVID19Vaccine@dph.ga.gov.
 - Second Offense -- Immediate Termination from the Program.
- For Providers who fail to report vaccine administration data into GRITS within 24 hours of administration:
 - First Offense – Written warning from DPH; however, if reporting is not corrected within 7 calendar days, a two-week moratorium on additional vaccine shipments shall be imposed and a corrective action plan developed and implemented to prevent future violations.
 - Second Offense – Two-week moratorium on additional vaccine shipments, as well as correction of reporting along with development and implementation of a corrective action plan to prevent future violations.
 - Subsequent Offenses – to be determined by the Commissioner of the Georgia Department of Public Health.
- For Providers who knowingly vaccinate recipients who do not live or work in Georgia:
 - First Offense – Written warning from DPH.
 - Second Offense – Two-week moratorium on additional vaccine shipments, as well as development and implementation of a corrective action plan to prevent future violations.
 - Subsequent Offenses – to be determined by the Commissioner of the Georgia Department of Public Health.

- For Providers who refuse to administer vaccine to recipients who live outside the county:
 - First Offense -- Written warning from DPH.
 - Second Offense -- Two-week moratorium on additional vaccine shipments, as well as development and implementation of a corrective action plan to prevent future violations.
 - Subsequent Offenses – to be determined by the Commissioner of Public Health.
- For Providers who fail to use all reasonable efforts to administer a second dose to vaccine recipients who received a first dose from the Provider:
 - First Offense -- Written warning from DPH.
 - Second Offense – Referral to the Provider’s professional licensing Board.

The Commissioner of the Georgia Department of Public Health shall have the authority to assess penalties and/or require other corrective action for other Program abuse and/or waste, up to and included termination from the Program based on the egregiousness of the abuse and/or waste. Other penalties and/or corrective action to address identified abuse and/or waste that may be imposed or required include, but is not limited to:

- Participation in education, in person or online, individually or in a group, to help Providers meet Program requirements;
- Modification of Supply;
- Cessation of Supply;
- Heightened Monitoring through on-site visits to confirm implementation of a Corrective Action Plan;
- Required submission of documentation of corrective action and cessation of vaccine ordering pending receipt of required documentation;
- Suspension from Program (minimum of 45 day suspension required for vaccinating outside of the current phase);
- Return of vaccine inventory during suspension period; and
- Termination from Program.

Should a Program Provider be suspended or terminated from the Program, said Provider shall, within 72 hours of receipt of the Notice of Suspension/Termination, voluntarily allow DPH staff entry to the facility to take possession of all vaccine previously delivered to the Program, except inventory needed for second dose vaccine recipient needs.

The DPH Commissioner will make the Final Determination regarding the Penalties assessed and/or Corrective Action required.

DPH/GIP Compliance Review:

DPH will confirm compliance with Program requirements by:

- Reviewing Georgia Registry of Immunization Transactions and Services (GRITS) for proof of reporting of Vaccine Inventory, Doses Administered, and Waste;
- Monitoring Provider Profiles, Inventory Levels, and Waste;
- Comparing COVID-19 Redistribution Agreement with Vaccine Redistribution; and
- Investigating complaints of abuse and/or waste as submitted to DPH-ReportFraud@dph.ga.gov, or through other channels.

Reviewing GRITS for Proof of Reporting of Vaccine Inventory, Doses Administered, and Waste.
DPH/GIP staff review GRITS to assess whether Providers are entering into GRITS the following information within the time specified:

1. Current vaccine inventory - daily.
2. Vaccine inventory received - upon receipt of delivery or within 24 hours of delivery.
3. Doses administered - within 24 hours of administration.
4. Waste due to failure to administer, temperature fluctuations, spoilage, and/or expiration - within 24 hours.

Monitoring of Provider Profiles, Inventory Levels, and Waste

DPH/GIP staff:

1. Review Provider profiles, which reflect an estimate of the number of COVID-19-eligible vaccine recipients the Provider expects to serve under each active phase (e.g., Phase 1A, Phase 1A+, Phase 1B, etc.) and are uploaded into the Centers for Disease Control and Prevention (CDC) - developed Vaccine Tracking System (VTrckS).
2. Review Provider profiles to assess whether Providers represent having appropriate vaccine storage and handling capacity.
3. May review a random Provider sample intermittently to compare data on vaccine ordered and/or doses administered and on hand inventory data against providers most recent submitted profile estimates.
4. May contact Providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed. GIP staff contact providers that exceed profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed.
5. May review Provider reporting regarding waste to confirm action taken to reduce waste includes, but is not limited to, administering all doses within a vial even if Provider must administer to vaccine recipients in accordance with the waste avoidance section of this policy.

Detection of Provider Abuse and/or Waste

DPH/GIP staff detect and/or prevent abuse and/or waste of vaccine supply by:

1. Intermittently cross-checking Provider information against the List of Excluded Individuals/Entities on the Department of Health & Human Services (HHS) Office of Inspector General website, as individuals or entities on the List of Excluded Individuals/Entities shall be excluded from the Program.
2. Reporting to the DPH/GIP Deputy Director unexplained amounts of inventory, doses administered, and waste, as trained DPH/GIP Program staff review vaccine administration reports for excessive use, underreporting, and other activities that may look out of the ordinary.

Any individual, group, or Provider who wants to report a suspected case of abuse and/or waste, should send an email to DPH-ReportFraud@dph.ga.gov with the following information:

1. Name of Provider (Medicaid ID if known) suspected of abuse and address;
2. Source of the allegation;
3. Source's name, address, and telephone number (if available)
4. A description of the reason for the report (i.e., suspected abuse)
5. Specific COVID-19 vaccine management requirement violated;
6. Value of vaccine involved (if available); and
7. A copy and/or summary of the complaint and the complainant's name, address and telephone number.

The DPH/GIP Deputy Director will review all reports submitted and, within five business days of the report, initiate a DPH/GIF staff investigation for all cases with sufficient evidence of abuse.