FAOs about Changes to DHR Immunization Rules and Regulations

1. What are the new immunization rules changes?

The new immunization rules changes include 1 new definition and changes in 4 vaccine requirements. These will become effective 7-1-07.

- The new definition is for "new entrant." This refers to any child entering any school or facility in Georgia for the first time or after having been absent from a Georgia facility for more than 12 months or one school year. A new entrant needs to be up-to-date on all the required vaccines. The term "new entrant" does NOT apply to children who simply move from one Georgia county to another, or from one school system to another in Georgia.
- There are 2 new vaccines required: •
 - Pneumococcal conjugate vaccine (PCV) is required for all children less than 5 years of age who are attending child care facilities, Head Start, or Pre-K programs. Children who have a high risk medical condition might receive an additional type of pneumococcal vaccine, PPV. Since this is not a requirement or a routine recommendation, it will not be documented on the 3231.
 - Hepatitis A vaccine or serologic proof of immunity is required for all children born on or after January 1, 2006 and who are enrolled in school or any of the above facilities or programs.
- There are additional doses added to 2 existing vaccine requirements for children entering • Kindergarten, 6th grade or new entrants into any grade (K-12).
 Mumps---2nd dose required or serologic proof of immunity
 Varicella--- 2nd dose required or healthcare provider documentation of disease

 - history or proof of serologic immunity.

2. Will children currently enrolled in school be required to meet the new immunization requirements or to get a new certificate?

Except for the situations listed below, children currently enrolled in schools, public or private, are required to meet the new rules that became effective 7-1-07. However, we encourage you to use this opportunity to educate parents and vaccinate children. Even though a child may not be required to meet the guidelines for additional doses of mumps or varicella vaccine, this is still an ACIP recommendation to help protect the child against these particular vaccinepreventable diseases.

These are a few exceptions to the above answer:

- Children enrolled in grades K-5 prior to 7-1-07 will have to meet the new requirements when entering 6th grade.
- Children who are currently enrolled and who do not have a certificate on file will be required to obtain a new certificate and to comply with the requirements in place at the time of their enrollment in a Georgia school.
- Children who are currently enrolled who might leave the school system for 1 year or • longer and then return, would then meet the definition of a "new entrant" and they would be required to abide by the new rules, regardless of grade level or age.

3. Will children who are already enrolled in childcare, Head Start, or pre-K be required to get the new immunizations?

• Yes, children who are already enrolled should get the newly required vaccinations appropriate for their age. However, they have until their current Certificate of Immunization expires to obtain any vaccines needed and to submit to the facility

documentation of receipt on the new Certificate of Immunization (Form 3231/Revised 3/2007).

- Children who are currently enrolled in 4 year old pre-kindergarten programs will be required to obtain the new vaccines if needed and submit documentation of meeting these requirements on the new Certificate of Immunization (Revised 3/2007) prior to or upon entry to school (5 year kindergarten). However, if a student has a Certificate of Immunization (Form 3231/Revised 10/2003) that is marked as "Complete for School Attendance," and the new requirements for 2 doses of varicella and mumps vaccines or proof of immunity are appropriately documented, he will not need to obtain the new Certificate.
- Children who are enrolled in school and also attend childcare or "after school programs" are required to have a copy of their current Immunization Certificate on file in both facilities. A child does not have to obtain a new certificate if he is already enrolled in a child care or after school program and he has a Certificate of Immunization on file that is marked as "Complete for School." However, we encourage you to use this opportunity to educate parents and vaccinate children. If a child does obtain vaccinations, a new certificate documenting the vaccinations should be completed and copies submitted to both facilities.
- **4. If I conducted inventories in the schools or child care facilities in my district before 7-1-07, what rules should have been followed when looking at immunization certificates?** Any audits done in childcare facilities before July 1, 2007 should have been based on the rules and regulations in place at that time.

5. After 7-1-07, what rules should I be following when conducting immunization inventories in childcare facilities and schools?

Childcare facilities:

- Children who have certificates that will expire after 7/1/07 are considered "current" until the documented "Date of Expiration" is reached.
- Children entering 5 year old kindergarten on or after 7/1/07 are required to obtain the new vaccines if needed and submit documentation of meeting these requirements on the revised Certificate of Immunization dated 3/2007. However, if a student has a Certificate of Immunization (Form 3231/Revised 10/2003) that is marked as "Complete for School Attendance," and the new requirements for 2 doses of varicella and mumps vaccines or proof of immunity are appropriately documented, he will not need to obtain the new Certificate.

Schools:

- Children entering 5 year old kindergarten, 6th grade and all new entrants into any grade must meet the new requirements and need to have vaccinations documented on the revised Certificate of Immunization dated 3/2007. However, if a student has a Certificate of Immunization (Form 3231/Revised 10/2003) that is marked as "Complete for School Attendance," and the new requirements for 2 doses of varicella and mumps vaccines or proof of immunity are appropriately documented, he will not need to obtain the new Certificate.
- Children currently enrolled in schools are not required to meet the new rules and do not have to obtain the revised Certificate of Immunization dated 3/2007. Exceptions are students entering 6th grade, and students who leave and return as "New Entrants." In these instances, students are required to obtain vaccinations required for their age and submit documentation on the new Certificate of Immunization (Revised 3/2007).

• Children who are currently enrolled and who do not have a certificate on file will be required to obtain a new certificate and to comply with the requirements in place at the time of their enrollment in a Georgia school.

6. What constitutes "proof of immunity" to varicella or chickenpox?

Any of the following can be used to document the immunization certificate for immunity to varicella:

- Documentation of age-appropriate immunization (1 dose for pre-school aged children, and 2 doses for children who are entering school at the kindergarten or higher level).
- Laboratory evidence of immunity
- A healthcare provider diagnosis of disease or healthcare provider verification of a reported history of disease. (For purposes of completing and signing Form 3231, this would need to be a licensed healthcare provider who is allowed to issue immunization certificates, which in most cases would not include school nurses.)
- For mild or atypical cases of disease, there should be a link to a typical case of chickenpox, or a link to an atypical case with evidence of laboratory confirmation of immunity if the testing was done at the time of the disease occurrence.

7. Why are these new requirements being put into place?

The Georgia Immunization Program has always followed the recommendations of the CDC's Advisory Committee on Immunization Practices or ACIP. For those who may not be aware, this group of physicians, academicians, and scientists meets 3 times yearly to discuss, evaluate, and make recommendations on the use of vaccines licensed in this country. They publish an annual schedule for adults, children, and adolescents.

The ACIP does not require that any of the vaccines become mandated by state law, but make recommendations based on the science and the data showing their effectiveness in disease prevention. So, for the 4 vaccines designated in Georgia's new requirements, this is a brief synopsis of the ACIP's recommendations:

- Pneumococcal vaccine----this vaccine first appeared on the childhood immunization schedule as a recommendation in 2001. Since that time, ongoing data collection about the vaccine and the incidence of invasive pneumococcal disease have shown the ability of the vaccine to greatly reduce the incidence of such disease in both vaccinated children under 5 years of age, and secondarily, among some adult contacts of those children.¹
- Hepatitis A vaccine----this vaccine was added to the recommended childhood schedule in 2000. At that time it was recommended for routine use in some states and regions because of their high rates of disease. The subsequent reduction in the incidence of hepatitis A disease in those areas has shown the value of this vaccine. Since 2001, rates in states where vaccination was recommended have greatly decreased and are approximately equal to the rest of the U.S.²
- Mumps vaccine---1 dose of mumps vaccine has been a childhood recommendation for well over 25 years. However, in part because of the huge outbreak of mumps disease in the Midwest in 2006, even among immunized persons, the ACIP voted last year to recommend a 2nd dose of mumps vaccine for school-aged children (K-12) and adults at high risk.³
- Varicella vaccine---varicella vaccine was added to the ACIP Recommended Childhood immunization schedule in 1996. One dose was recommended for children ages 12-18 months, with catch-up at 11-12 years of age. Ongoing study of the vaccine and disease incidence since that time have shown that there continues to be significant numbers of vaccinated children who still experience "breakthrough" disease. It can be difficult to

know if the child develops immunity from this mild form of the disease, so to truly determine this may require laboratory testing of a lesion or a serologic test. Though it is generally a milder form of the disease than "regular" chickenpox, it still causes the child to be ill; it is contagious; and it causes great disruption in schools. In 2006 the ACIP voted to recommend a 2^{nd} dose of the vaccine for children, adolescents, and adults who previously had only received 1 dose.⁴

8. Where can I take my children to get these vaccines?

You can generally obtain these vaccines at your provider's office or through any public health clinic.

9. Does Vaccines for Children (VFC) cover the vaccines required by these new regulations?

Yes, for children who are eligible for the Georgia VFC Program, the doses of vaccine required by the new rules and regulations will be covered by that program. VFC vaccine may be used for children who are insured but whose insurance does not cover that particular vaccine. For insured children whose insurance covers vaccines, but the policy has a high deductible, the child is still considered to be fully insured and, therefore, not eligible for VFC vaccine.

10. Is it true that Georgia has a registry that keeps track of a person's immunizations?

Yes, the Georgia registry is called GRITS, which stands for the Georgia Registry of Immunization Transactions and Services. It is a web-based program designed to store an individual's immunization records from birth to death. It is available to all healthcare providers in the state as well as schools and colleges. All providers that give immunizations are required to enter them into GRITS.

11. Does GRITS handle the new rules and what shots will print on the Georgia Immunization Certificate, Form 3231?

The ACIP recommendations regarding timing and spacing of these vaccines, and all routinely recommended childhood and adult vaccines, have been incorporated into the tables set up in the registry system. So, all vaccine doses are recommended, evaluated, and verified as valid or invalid in GRITS, based on the ACIP recommendations.

- When printing a certificate of immunization, GRITS will print the dates for those vaccine doses that are required for school or childcare in the top section for Required Vaccines.
- Extra doses of required vaccines will be found in the child's history in GRITS, but will not print on the 3231.
- In the space for Recommended Vaccines at the bottom of the new 3231, dates the child received those vaccines will be documented in GRITS and will print on the 3231. For persons filling out this form by hand, we request they write in those dates to make the form more complete, but they are not required to do so.
- If vaccinations are needed, GRITS calculates a "date of expiration" based on school or childcare requirements. For instance, should a child receive Hepatitis A vaccine, though he or she may not be required to have it because they were born before 1-1-06, the doses will still be documented in the hepatitis A section on the form; however, the date of expiration will not be affected by the need for the child to come back for the 2nd dose. The parent and the physician or clinic administering the vaccine and will be required to keep up with that return appointment information.
- Since the GRITS system is based on ACIP recommendations, it will calculate the validity of vaccine doses based on the minimum ages and time intervals, including the use of the 4-day "grace period." It will not recommend that vaccine doses be given

during the grace period, but will accept doses already administered during the 4 day period before the recommended minimum age or interval.

• Since GRITS has been modified to reflect the new recommendations for varicella and mumps vaccine, the earliest and recommended dates for administration of the 2nd doses of these vaccines might indicate the 4th birthday, even for children older than 4. This will be reflected in the appearance of a past-due expiration date on Form 3231. When these doses are given, the certificate will then reflect the child's current status: either a current date of expiration or complete for school.

12. Though it is not a new requirement included in the rules changes, what are the regulations regarding who can legally sign the immunization Certificate, Form 3231?

The GA Code, Section 20-2-771 and DHR Rules and Regulations, Section 290-5-4-.05, state that the form must be signed by a physician licensed in the State of Georgia or by a qualified employee of a local Board of Health or the State Immunization Program. The physician may delegate the responsibility of affixing his signature to the form, but this must be accompanied by the signature of the person completing the documentation.

13. My clinic has a software system we use to print immunization certificates. How can we print the new certificate now?

Georgia DHR Rules and Regulations address Certificates of Immunization as follows: "Immunization shall be deemed to exist when certification is made by a physician or a qualified employee of a local Board of Heath or the State Immunization Program, on a form provided by or approved by the Department of Human Resources, that a named person has been vaccinated against a specific disease in compliance with Section 290-5-4- .03 of this Chapter." Therefore, providers who have or want to utilize a medical software system for printing Certificates of Immunization need to contact the Georgia Immunization Program and request permission and assistance to incorporate the state form into their systems. Once they have done that, they will need to get the approval of the Georgia Immunization Program to begin printing that form from their system. Approval is granted only for certificates that reflect the exact information contained on the state issued certificate. If providers choose not to do that, or are unable to put the form into their system, they will need to print the Georgia Department of Human Resources Certificate of Immunization (Form 3231) directly from GRITS or complete a hard copy of this form that is available from the Georgia Immunization Program.

14. Where can I get more information about the new immunization requirements?

Parents, providers, schools, childcare facilities, and the public in general can get information about the new immunization requirements from their healthcare provider, either public and private, or from the Georgia Immunization Program website at www.health.state.ga.us/programs/immunization There is a link there to samples of all the forms, instructions, and requirements, as well as to the actual DHR Rules and Regulations document approved by the DHR Board on 2-21-07.

15. In the event of vaccine shortages or shipping delays, how should healthcare providers, schools, and facilities handle immunization certificate documentation and follow-up? The responsibility of the school or facility is to ensure that appropriate documentation is on file. Students are considered to be in a 'waiver period' for 30 days beginning with the first day of attendance. Once the waiver period has passed, each student enrolled must have an appropriate certificate on file. This includes a Form 3231 with "Complete for School Attendance" checked; or a Form 3231 with a future date of expiration; or appropriate exemption or proof of

immunity documentation, if applicable.

Some new students and 6^{th} graders may have 3231 forms with an expiration date in the future. In this event, the following guidance applies:

- These certificates are valid until the expiration date.
- Schools are advised to notify the parent prior to the expiration date and to require an updated Form 3231.
- In an audit situation, a Form 3231 with a date of expiration in the past is considered invalid and counts against the school or facility's compliance rate.
- In the event of a vaccine shortage or delay, the provider may draw a line through the date of expiration; write in a new date based on the anticipated availability of vaccine; date and sign it, and note "vaccine delay" or similar message to indicate the reason for this alteration of the form.
- Providers will need to include such children in their recall system so that they can be contacted when vaccine is received in the office.
- Schools and facilities will need to maintain a tickler system to file certificates with expiration dates so they can be sure to remind parents about the need for appropriate documentation for their child's school record.

¹MMWR, "Direct and Indirect Effects of Routine Vaccination of Children with 7-Valent Pneumococcal Conjugate Vaccine on Incidence of Invasive Pneumococcal Disease---United States, 1998---2003," September 16, 2005/54 (36); 893-897.

²Centers for Disease Control and Prevention. Prevention of Hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006:55(No. RR-7):5.

³MMWR, Notice to Readers, Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Control and Elimination of Mumps, Early Release Vol. 55/June 1, 2006.

⁴ACIP Provisional Recommendations for Prevention of Varicella, accessed at http://www.cdc.gov/nip/vaccine/varicella/varicella_acip_recs_prov_june_2006.pdf