Kansas Newborn Screening Program Policy Change

Amending Collection Information on Newborn Screening Specimen Submission Forms

The Kansas Newborn Screening Program (KS-NBS) strives to protect and improve the health of all newborn Kansans. In review of current practices, KS-NBS is updating the policy and will no longer honor requests to change the collection information provided on the newborn screening dried blood spot specimen submission form. This change is produced from efforts to ensure timely and reliable newborn screening results and subsequent follow up.

A. Policy Change

Effective Oct. 1, 2018, when a newborn screening (NBS) dried blood spot (DBS) specimen is received by the state laboratory and the birth and/or collection date and/or time entries are missing or illegible, the specimen will default to less than 24 hours of age from birth, and an "INVALID" result will be generated for certain tests (see paragraph C.II.). Only date and time entries written into the appropriate boxes of the NBS DBS submission forms will be used to calculate the age of the newborn at specimen collection. Labels will not be accepted as valid demographic information.

Once an "INVALID" report has been generated, amendments to the date or time entries will not be made, and a repeat specimen will be required.

B. Impact on Newborn Screening Process

I. Facilities submitting NBS DBS will no longer be able to submit amended report requests to change the date and/or time of birth or date and/or time of collection.

II. An increase in the number of invalid specimens will occur initially. Consequently, an increase in the number of repeat screens will follow.

III. As submitting health care facilities recognize this increase[1], they will be encouraged to provide more accurate and complete submission forms to combat the rise in invalid specimens.

IV. The initial increase in repeat screens due to this change may cause more screens to be collected at pediatric care facilities and other NBS DBS submitting facilities rather than birthing facilities.

[1]Facilities must track their invalid statistics per GEN.41325 Newborn Screening Results Phase II, Clinical and Laboratory Standards Institute, NBS02-A2: Newborn Screening Follow-up. The standards state that the submitting facility must have a procedure for handling invalid and positive newborn screening results for samples submitted to other laboratories for testing.

C. Reasoning and Situational Background

I. Importance of Accurate Collection Information

Accurate dates and times of birth and collection entries provided on the submission form are necessary to provide newborn screening results accurately and in a timely manner. When this vital information is not submitted or is illegible, the age of the newborn at the time of the specimen collection cannot be calculated, thus creating a major and unnecessary delay in processing the specimen.

When the date and time of collection are recorded/documented after the analytical testing has been completed, the entire newborn screening process is affected. This change may cause a need for: different cutoffs to be applied to the results, results to be re-evaluated for each testing category, and/or the laboratory report to be amended with notification to primary care physicians and the Follow Up Program.

By not allowing collection information to be amended, a greater importance is placed on the provision of legible and accurate entries for date and time of birth as well as date and time of collection.

II. Validity of Results

Results for primary congenital hypothyroidism, congenital adrenal hyperplasia, organic acid disorders, amino acid disorders, and cystic fibrosis are not reliable in specimens collected less than 24 hours from birth due to the nature of the corresponding analytical tests. Reports for specimens received with missing or illegible collection information will default to less than 24hrs and the above test results will be reported as “INVALID”. Screening results for galactosemia, hemoglobinopathies, biotinidase deficiency, severe combined immunodeficiency, and fatty acid disorders will be reported as the results are valid in specimens collected before 24 hours of age.

III. Modifying a Legal Document

The NBS DBS submission form is the legal document describing the condition, date and time of collection, as well as date and time of birth. Making a major amendment to this form, which subsequently modifies the lab results, raises speculation regarding the validity of said amendment. This policy will remove any possible doubt associated with the modification of the information on the submission form.

D. Conclusion

This policy change is one example of the steps taken daily within KS-NBS to improve screening and follow up processes to ensure every newborn in Kansas receives quality screening care. Every submitting health care facility can assist the impact of this policy by submitting complete and accurate demographic information in the appropriate boxes of every NBS DBS submission form. By improving this process, the KS-NBS and all newborn screening partners will advance in the mission to provide quality newborn screening care to all newborn Kansans.