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STATEMENT BY TENNESSEE HEALTH COMMISSIONER LISA PIERCEY ON CONCLUSION OF INVESTIGATION OF SHELBY COUNTY COVID-19 VACCINE MISMANAGEMENT

NASHVILLE, Tenn. – The Tennessee Department of Health, with the assistance of the Centers for Disease Control and Prevention is nearing completion of a month-long investigation into the COVID-19 vaccine handling procedures at the Shelby County Health Department.

TDH recognized staffing and operational challenges in SCHD field sites in late January and provided additional support, including deploying FEMA resources, in early February. TDH was made aware of over 1,000 expired doses on February 19, prompting deployment of TDH staff and resources to SCHD.

TDH staff identified multiple contributing factors resulting in vaccine mismanagement including suboptimal and unusual pharmacy operations, a lack of standard operating procedures for storage and handling of vaccine, insufficient and disorganized recordkeeping and a deficient process for management of soon-to-expire vaccine doses resulting in multiple wastage events.

This investigation was a herculean effort involving multiple state and federal agencies including TDH, the CDC, HHS, Operation Warp Speed and the FDA, as well as notification of the White House. Additionally, scientists and executives from both vaccine manufacturers, Pfizer and Moderna, were frequently integrated into discussions of the Shelby County situation to provide expertise into vaccine stability of their specific products.

The first phase of this response focused on inventory assessment, management and ultimately the transfer of all physical inventory and vaccine operations to the City of Memphis, as well as a detailed accounting for all expired doses. In total, there were 2,510 vaccine doses that were expired or wasted at SCHD, dating back to February 3. Other critical issues which were quickly resolved included movement of soon-to-expire excess inventory and other previously unreported vaccine handling and administration issues.

Following successful transition of vaccine operations in the first phase, TDH and CDC worked closely with SCHD officials to comprehensively assess cold chain management and administration of vaccine doses given at SCHD sites between the dates of December 28 through February 24. Due to the previously described deficiencies in record keeping, this was an extensive and painstaking analysis. Information was gathered from vaccine storage units, digital data loggers, all available handwritten temperature logs and hours of personnel interviews. Between TDH and CDC, it is estimated that over 1,000 hours of public sector manpower over the last 25 days was dedicated to this massive undertaking, which sought to

ensure the effectiveness of almost 55,000 doses given during this date range.

Following a review of all findings with both Pfizer and Moderna scientific teams, the final determination by TDH, SCHD, FDA and CDC is that vaccine stability remained intact for the dates in question. CDC has finalized its report confirming vaccine stability and has provided that to both TDH and Shelby County leadership, as of this morning. Because of the exhaustive assessment by local, state, federal and industry partners, we can confidently reassure all recipients of vaccine at Shelby County sites that the doses received were stable and effective.

Going forward, TDH will conclude its work and demobilize from the SCHD site. An after-action review and a full written report will be forthcoming in the next few weeks and will be presented to Mayor Harris and the SCHD leadership, in an effort to continuously improve its public health services. TDH and SCHD collaborate on public health activities including other critically important vaccine work such as the Vaccines for Children Program, which is currently under CDC review. In its report provided this morning, CDC officials were clear that the report provided today did not include an analysis of the other issues surfaced during their visit, including recordkeeping, program oversight and inventory management, and that the CDC's Immunization Services Division would continue to be engaged in this review.

COVID-19 vaccine delivery has been a fast moving and complex response effort. Future implications for resuming COVID-19 vaccine activities at SCHD will require improved vaccine inventory management, timely reporting of issues identified and a renewed emphasis on the importance of record keeping. SCHD has expressed their ongoing commitment to the administration of COVID vaccines to Shelby County residents through movement of state-funded vaccine strike teams and discussions around further integration of SCHD nursing staff into the currently vaccine delivery mechanism.

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