

**MONTVILLE TOWNSHIP BOARD OF HEALTH
REGULAR MEETING MINUTES
April 12, 2021 at 7:30 pm**

Members Present

Mr. Charles Perry
Dr. Arnold Pallay
Ms. Betty Bowers
Dr. Steven Tuckman*
Dr. Sunil Shah
Dr. Nisha Jani**

Members Absent:

Dr. Sachin Shah

Others Present:

Aimee Puluso, Health Officer
Amanda Rizzo, BOH Secretary
Alix Claps, Esq. on behalf of David Pennella, Esq.
Dr. Matthew Kayne, Twp. Committee Member
June Hercek, Assistant Township Administrator
Dr. Steven Marcus, Member of the Public
Anonymous Caller from the Public
Dr. Sherif Nasr, SiParadigm Diagnostic Informatics
Dr. Chiraag Patel, P4 Clinical LLC
Melissa Benno, Member of the Press

Call to Order and Roll Call

With a quorum present, Mr. Charles Perry called the meeting to order at 7:32pm.

As required by the Open Public Meetings Act (a.k.a. “Sunshine Law”), adequate notice of this meeting was provided. The notice specified the meeting was to be held at 7:45 p.m., in the Health Department at the Montville Township Municipal Building, 195 Changebridge Road. Legal notice of this meeting emailed to The Daily Record Newspaper, posted on the public bulletin board in the lobby of the Municipal Building, posted with the agenda on the Montville Township website at www.montvillenj.org, filed with the Montville Township Clerk.

Ms. Rizzo took a roll call of members present.

Approval of Minutes

MOTION: A motion was made by Mr. Perry, to approve the Regular Minutes of the Board of Health Regular Meeting held on March 8, 2021. Seconded by Dr. Pallay. Ms. Rizzo took a roll call of members present – all in favor, motion passed.

Public Comments

MOTION: A motion was made by Mr. Perry to open the meeting to public comments from any citizen wishing to speak before the Montville Township Board of Health. Seconded by Dr. Sunil Shah. Ms. Rizzo took a roll call of members present – all in favor, motion passed.

Ms. Bowers asked that since the public portion comment section is in the beginning of the meeting, would the public lose the ability to ask additional questions if say they had a question at the end of the meeting.

Ms. Puluso answered that the public comments portion is the only opportunity during the meeting when the public can comment or ask questions. If there are additional question and/or comments from members of the public, they may contact Administration via email and those questions and/or comments will be addressed at the next regular meeting. Ms. Bowers thanked Ms. Puluso for clarifying.

Dr. Marcus had a comment regarding an article in today's Patch with respect to the COVID numbers which he believes are disturbing. Dr. Marcus stated that the article indicated that Lincoln Park, Montville, and Boonton have relatively high rates of infection compared to the rest of the State. The numbers are in rank order. Montville is listed at 152 out of over 600 communities, for number of cases, and rates of cases at 363rd; Lincoln Park rated at 58 for number of cases. Dr. Marcus asked if Ms. Puluso had interaction with the communities that border the Township, regarding these high rates of infection. Dr. Marcus asked if there were regular or impromptu meetings or interaction with these communities to address this situation. Ms. Puluso stated that as President of the Morris Regional Health Public Partnership, she holds weekly virtual meetings with the Health Officers throughout Morris County and thus is in regular communication with them. Ms. Puluso stated that with respect to those specific numbers, they have been artificially inflated by over 300 cases due to a lab reporting errors. Until that issue is resolved, the numbers of reported cases by the County and State are incorrect. Ms. Puluso stated that the case numbers reported by Montville Township on the COVID-19 page of the Township website are correct. Dr. Marcus asked Ms. Puluso if she looked at the numbers reported in the Patch, as they look pretty close to the numbers that Montville's Health Department is reporting. Ms. Puluso stated that she had not looked at the article. Dr. Marcus requested that Ms. Puluso review the article. Ms. Puluso stated that she would do so.

* Dr. Steven Tuckman had joined the meeting at 7:38p.m.

Ms. Puluso asked if there were any questions or comments from the public for any items on the agenda. There were no questions or comments.

Ms. Puluso asked if there were any questions or comments from the public for any items not on the agenda. There were no questions or comments.

MOTION: A motion was made by Mr. Perry to close the meeting to public comments from any citizen wishing to speak before the Montville Township Board of Health. Seconded by Ms. Bowers. Ms. Rizzo took a roll call of members present – all in favor, motion passed.

New Business

Ms. Puluso stated for the record that Alix Claps, Esq. was representing the Board of Health for this evening in lieu of David Pennella, Esq. who was absent due to medical reasons.

Public Hearings (2):

Each of the two public hearings were held due to reporting errors on the part of two commercial laboratories, both located at 25 Riverside Drive, P4 Clinical and SiParadigm Diagnostic Informatics. Both of the labs reported positive lab results with the laboratory address in Montville listed as the residential

address of the patient. This causes these cases to be erroneously attributed as cases of Montville residents. For SiParadigm, there have been at least 25 of these errors since the beginning of the pandemic. For P4 Clinical, there was an incident with 300 of these errors on a single day in March, and several prior to that since the start of the pandemic. For each one of these errors, the Health Department must spend an inordinate amount of time trying to contact the laboratory to notify them of the error, and follow up with them until the error is corrected. Ms. Puluso stated for the public and as a refresher for the Board, for COVID-19 and all other reportable communicable diseases: when a laboratory tests a sample, they are required by the State of New Jersey to upload the results of that test to the electronic Communicable Disease Registry Surveillance System (CDRSS). The Health Department for the municipality where the patient lives is notified through that system that there is a communicable disease that needs to be investigated. The communicable disease investigators, which are usually the Public Health nurses and now with COVID also includes Contact Tracers, then investigate each of these cases. Ms. Puluso stated that the Montville Health Department, as well as other municipalities where labs are located, have had issues since the beginning of the pandemic with cases being assigned incorrectly. Ms. Puluso stated that this has been communicated to the labs with varying degrees of success. Ms. Puluso stated in fact, if an address is not provided and it is changed to unknown, it will sometimes be reverted back to the lab address by the State, since that is the only address in the record. Cases with where the lab address in Montville is listed as the patient address causes the case numbers and other statistics reported by the county and the state for Montville Township to be incorrect, in this case, artificially inflated by several hundred cases. Ms. Puluso stated that the number of cases reported by the Health Department on the COVID-19 page of the Township website are accurate, as that number includes only the actual Montville resident cases. Ms. Puluso stated that usually one or two incorrect cases are reported at a time, and corrected as they occur. Most recently, 300 cases were received and assigned to Montville Township in a single day, which was reported by the county and the state, and which caused concern from the public. Ms. Puluso stated that the Health Department reached out to the two laboratories for more information and to discuss the reason for these reporting errors, especially in regards to the 300+ cases from P4 Clinical. Ms. Puluso issued Notices of Violation to both labs and copied the State, and to ensure accurate information and transparency regarding this issue for the public, also requested both labs to appear before the Board of Health at their regular meeting to explain why these reporting errors occurred, what has been done to correct them, and what has been done to prevent them from occurring again going forward. Responses to the Board from the two labs have also been provided in writing.

Public Hearing #1 – SiParadigm Diagnostic Informatics.

Ms. Puluso introduced Dr. Sherif Nasr, the Medical Director of SiParadigm Diagnostic Informatics, 25 Riverside Drive, Unit 2, Pine Brook. Ms. Puluso asked if any of the Board Members had questions for Dr. Nasr before he begins. Mr. Perry thanked Dr. Nasr for coming to the meeting, and asked him to explain lab procedures, how many cases the lab handles on a particular day, the methods of transportation of the samples, whether or not they follow a chain of custody process, whether or not the samples matched up with the patient demographics, and asked for clarification on their quality control process.

Ms. Claps reminded the Board that witnesses must be sworn in prior to giving testimony, and swore in Dr. Nasr. Ms. Claps asked Dr. Nasr to state his name and who he was representing for the record. Dr. Nasr stated his full name and that he is the Medical Director of SiParadigm Diagnostic Informatics.

Dr. Nasr stated that Paradigm Laboratory specializes in testing for cancers and blood diseases. However, since the inception of the pandemic the laboratory started providing PCR testing for COVID in late May of 2020. The number of cases goes up and down but since the pandemic, on average three to four thousand tests are processed every day, about two-thirds from nursing homes. Both Governors Cuomo and Murphy have executive orders that all nursing home staff (and some patients) are tested on a weekly basis, sometimes twice a week. Additionally the laboratory services nursing homes outside the New Jersey and New York areas as well as hospice centers nationwide. A quarter of the laboratories specimens come from local pharmacies with walk-in-patients. The laboratory has an inflow web portal system that generates bar codes using portable printers at the site of specimen collections. Positive specimen identification is maintained and checked by matching to specimen bar codes. There are two platforms, so if a borderline result is received, it's tested on a different platform to confirm the results. SiParadigm is responsible for a total of (26) twenty-six cases that were incorrectly reported as Montville residents, and that he and a family member account for two of those cases. Fifteen of those cases were other lab employees. The reporting system had a glitch, with the lab reported the employee's work address rather than their home address. There were nine additional cases that were collected from pharmacies where patients were undocumented and either put a wrong address, or left it blank. SiParadigm's intake system was not smart enough to catch this and it defaulted to the lab address. The Health Department had contacted SiParadigm regarding these errors and the lab has not been as responsive as they should have been, partly because of the stringency with HIPAA, and also due to poor follow-up on the lab's end.

Mr. Perry commented positive sample control begins with the demographics at the point of collection. The lab or pharmacy tech collecting the data, regardless of whether it is paper form or electronically entered, it is a matter of quality control to catch the errors. Mr. Perry asked about staff training, and noted the impact on people's lives that this type of error can have, and that it is imperative to get the proper information, to follow through with the proper quality control, and to ensure training of staff.

Dr. Nasr answered we do high complexity testing, which is a highly regulated process that all laboratories follow in terms of specimen identification and chain of custody. Each specimen has two unique patient identifiers at all times. The only error was with the addresses which has happened at a rate of 0.05%, or (1) out of every 2,000 specimens. The lab will not receive specimen if username, password, and telephone number are incorrect. Dr. Nasr reiterated that the laboratory processes 3,000 to 4,000 cases a day and the number that had issues was nine (in addition to the 17 lab employees that incorrectly entered their work address instead of their home address). Ms. Puluso stated that as of today there were additional incorrect cases that came in after she communicated with the lab by email regarding corrective actions. Dr. Nasr stated those four cases were laboratory workers and were able to trace it to lack of updating of the CDRSS database after we updated our own data base. Their correct address was added to each case in CDRSS. Ms. Puluso stated that if these corrected addresses are entered as additional addresses, instead of modifying the primary address, it can cause the case to still be attributed to Montville. A laboratory employee may have to manually modify the primary address on each of these cases. Ms. Puluso reiterated the most important aspect that Mr. Perry discussed, which was about this not just a clerical reporting error, but more concerning, inaccurate addresses delay notification to, and contact tracing and investigation by, the appropriate health authority. Dr. Nasr agreed.

Mr. Perry asked what has been done to correct the issue. Dr. Nasr stated that the response was two-fold. Each of the cases have had their addresses corrected by the lab, and the lab's web portal intake system has been upgraded to detect blank addresses and highlight them. Before those addresses would just default to the lab address. The laboratory is performing manual oversight so when the address is incomplete or the alpha numeric are incorrect, they are highlighted and reviewed.

Dr. Jani thanked Dr. Nasr for his update and appreciated that he now has a process in place, but wondered what the timeline is for corrections going forward? Dr. Nasr stated that there was a delay initially, but since he has been in communication with Ms. Puluso, he has worked on correcting the system right away. The four additional cases reported this morning were investigated and corrected by the lab the same day.

Dr. Pallay asked for clarification on the specimens that had no address, and wanted to know if, other than the cases for the lab staff, were there any others without telephone numbers and proper addresses. Dr. Nasr stated that it is hard to tell, but the ones in question were not Montville residents. There is a system in place to ensure an address is entered, but it cannot detect if the address is falsified. Dr. Pallay asked how the lab can accept specimens without a driver's license or proper identification, or verification from the submitting source, such as nursing homes or minute-clinics etc. Dr. Pallay stated that it seemed accepting specimens without this verification is completely inappropriate. Dr. Nasr stated that a scan of driver's license is done but not matched with the address that is inputted into their system. Dr. Pallay stated with all due respect, that this whole situation was inappropriate. Mr. Perry agreed with Dr. Pallay. Dr. Nasr stated that it would be prudent to check cases to make sure that the driver's license on the intake matches their web portal system and he will institute that change.

Dr. Pallay asked what the Board's options and outcomes were in regards to this issue for these labs. Ms. Puluso stated that the Board may continue with additional public hearings if the issue has not been resolved to the Board's satisfaction. Additionally, the Notice of Violation issued by the Health Department was a formal warning. If the issue is not resolved, or occurs on a large scale again in the future, the next step will be to issue a summons for the lab to appear in municipal court. Ms. Puluso was hopeful that Notices of Violation and public hearing would be sufficient to resolve the issue and prevent it from occurring again in the future, and that issuing summonses to court could be avoided. Ms. Claps concurred with Ms. Puluso, and added that there are additional options as well, including a question of license renewal in the future. Ms. Puluso thanked Ms. Claps and noted that the State issues licenses to laboratories, and that all appropriate state agencies have been notified and copied on all communications in this matter.

Ms. Puluso stated for the record that Melissa Benno, a member of the Press, had just joined the meeting.

Ms. Puluso asked if there were any further questions for Dr. Nasr. There were no further questions.

Public Hearing #2 – P4 Clinical.

Ms. Puluso introduced Dr. Chiraag Patel, the Medical Director of P4 Diagnostics. Ms. Puluso stated that on March 12, 2021, the Health Department was notified through CDRSS of 303 COVID cases, all with the address listed as 25 Riverside Drive and linked to this laboratory.

Ms. Claps swore in Dr. Patel. Ms. Claps asked Dr. Patel to state his name and who he is representing for the record, and he responded: Dr. Chiraag Patel, Medical Director of P4 Clinical LLC.

Ms. Puluso stated that the Health Department had received a written response from Dr. Patel, and that it had been forwarded to the Board of Health members for their review prior to the start of the meeting.

Mr. Perry commented that quality control is imperative to catch errors before they cause a problem. He asked about staff training in this regard.

Dr. Patel stated that his laboratory follows a very similar, if not an identical, procedure as Dr. Nasr's laboratory in sample collection and test ordering. Dr. Patel's laboratory has an affiliate company that provides electronic medical record software. For example, if a physician orders a test, that sample is then accessioned through that electronic system. Samples are received in the lab through both paper requisition and electronic order. Those samples are then reconciled into the lab's system.

Mr. Perry asked if each sample was assigned an identifier which corresponds with the patient demographics. Dr. Patel responded yes, but in some instances where paper requisitions are received, those documents sometimes arrive incomplete. The lab has instituted a customer service process called "MIRP" (Missing Information Resolution Process). The customer service team contacts the ordering healthcare physician or supervising healthcare professional and obtains the correct patient demographic information.

Mr. Perry asked when the system was instituted and how long has it been in use. Dr. Patel responded that recently it became more utilized as volumes had grown with COVID-19. The lab has become much stricter in collection and verification of client information. Staff are being trained in collecting the correct patient demographic. Dr. Patel stated that the downside of not collecting the correct information for lab itself was both incorrect public health reporting and also billing, as the lab cannot bill clients if they do not have the correct information.

Mr. Perry asked about staff training and oversight. Dr. Patel responded that a full competency assessment program has been instituted where they train new employees on the proper accessioning procedures and verify that they are competent on a daily basis under direct supervision. Mr. Perry asked if they have oversight from the State of New Jersey? Dr. Patel responded yes, and that would fall under the General Lab Procedure Guidelines.

Ms. Puluso asked for clarification on "MIRP". Dr. Patel responded that the system has been instituted for 2.5 years but has been used more stringently since the onset of the pandemic. Dr. Patel indicated that their volumes prior to the coronavirus were averaging 150 to 300 samples per day. At the peak of the coronavirus the daily caseload was averaging roughly 4,000 to 5,000 cases per day. In order to handle this type of volume, the quality controls had to become much more stringent with how the information was handled.

Mr. Perry asked if staff had increased to keep up with the volume of cases. Dr. Patel stated that the molecular lab and accessioning team was a total of 10 staff members which was a mix of full time and part time workers. The accessioning team has grown from 4 to 16-20 workers. Mr. Perry asked what kind of

training was provided. Dr. Patel stated that staff is trained on how to accession the cases, appropriate procedures, and how to identify cases where there is incomplete information. Those cases that are incomplete are flagged and passed to customer service for follow up.

Mr. Puluso asked that “accession” be defined. Dr. Patel stated that the definition of accession is when a lab receives a patient case with a test requisition form, the lab then enters that information or reconciles that information into their own system and creates an accession number.

Mr. Perry asked if intake staff are audited by the supervisors to ensure that they are handling the processing correctly. Dr. Patel stated that they do quality checks for accessioning errors, daily.

Ms. Puluso asked for Dr. Patel to provide some insight on the 300 cases that appeared overnight on March 12th.

Dr. Patel responded that they receive samples in their New Jersey lab and accessioned those samples. These samples came from many different states in the country. They also have a lab in New York City to handle overflow, given the large volume of cases coming into the lab since the pandemic. For the 300+ case in question, the samples were sent from the lab in New Jersey to the lab in New York City to be tested. Software called Vital Access is used between the two labs. When one case is accessioned from one lab to another, then tested and passed back, it is not a seamless transition. In that transition in passing the data back, the patient demographic was somehow lost. The majority of the 300+ cases were not recent, but from early November, and at that time, the patient cases were reported back to the ordering physician and the public health results were reported back to the correct jurisdictions for public health investigation and contact tracing.

Dr. Patel further stated that there was a software glitch in mid-March where those cases that were tested months ago, were retransmitted into CDRSS with our 25 Riverside Dr. address showing as the patients’ primary address. Dr. Patel stated that when his lab was notified by the Health Department, they went back and collected the appropriate demographic information (which had been inputted initially), and updated CDRSS with the appropriate information. The challenge was in updating CDRSS with the appropriate patient information. The lab was still listed as the primary address. The majority of these 300+ patient cases do not even live in the State of New Jersey. Currently, the lab is working on is going through CDRSS and manually amending these cases to reflect the appropriate address of the patient.

Mr. Perry stated that it sounds like miscommunication between the two labs. Dr. Patel stated incompatible software is to blame. Mr. Perry asked if the NY lab was owned by P4 Clinical. Dr. Patel answered, no, it is a contracted lab. Mr. Perry asked whether or not the software was checked prior to this incident to see if it was compatible. Dr. Patel stated that it had been prior to this different version, which was designed in response to the pandemic, and that it is not a perfect solution. Mr. Perry stated that Dr. Patel should stay in contact with his information technology department. Dr. Patel stated that he will.

Ms. Puluso stated that she was concerned as to whether or not these people were able to have contact tracing done, and in a timely manner. Ms. Puluso asked Dr. Patel to confirm that this was handled correctly once error was rectified and all reporting was done to the appropriate jurisdictions. Dr. Patel confirmed

that the correct State and Local Public Health Departments were notified. Ms. Puluso stated that as of today's date, the county and state are still reporting case numbers that were 300+ cases higher than the accurate number, and asked Dr. Patel to explain this discrepancy. Dr. Patel said that the lab will be manually updating the cases in the CDRSS system one by one, and it is a slow process.

Dr. Sunil Shah asked for clarification regarding the 302 cases, and whether or not they were New Jersey residents. Ms. Puluso reminded the Board that Dr. Patel had stated previously in his testimony that the majority of these cases were not New Jersey residents. Dr. Patel stated the majority was from Michigan, Florida, Texas, and Pennsylvania. Dr. Shah asked if those states were notified. Dr. Patel stated those states were notified. Dr. Patel stated that the error occurred during a re-transmission of data.

Dr. Pallay asked Dr. Patel to clarify that these 300 cases were not from the last day or two, they occurred in weeks, were retransmitted, were not local, and they all did have appropriate addresses originally. Dr. Patel stated that is correct. Dr. Patel stated that this was a singular event.

Ms. Puluso noted that when these errors had occurred in the past, it was a handful at a time, and were correct relatively quickly.

Ms. Puluso asked if there were any additional questions for Dr. Patel. There were no additional questions. Ms. Puluso ended the public hearing, and thanked Dr. Nasr and Dr. Patel for coming before the Board, and stated that she hoped this issue could be resolved quickly.

Other new business – National Public Health Week.

Ms. Puluso stated that this was National Public Health Week (NPHW) (April 5-11, 2021) and that this information was also included on the COVID-19 page of the Township website. NPHW is celebrated every year in the first week in April, and includes a variety of virtual events including educational seminar, family trivia nights, and Instagram scavenger hunts. This year's theme was "Building Bridges to Better Health". In recognition of NPHW, Ms. Puluso had requested, and the Township Committee agreed and issued, a Proclamation declaring April 5 to April 11, 2021 to be National Public Health Week in Montville Township. Ms. Puluso stated that Senator Pennacchio also issued a similar proclamation at her request, and that he read the Proclamation in the State Legislature. In addition, Governor Murphy also issued a Proclamation declaring National Public Health Week in the State of New Jersey.

Ms. Puluso stated that, also in recognition of NPHW, as the Treasurer of the New Jersey Environmental Health Association, she suggested to the association, and they agreed, to purchase a yard sign for each individual local health department (104 in total) in the state to thank public health workers for their efforts. The signs include the Public Health logo and the message of thanks to the local public health departments. The signs were delivered by the Executive Committee of New Jersey Environmental Health Association to each health department so that they could be displayed outside local municipalities' municipal buildings. Montville Township's sign is displayed next to the municipal building's electronic sign so it was visible as people drove by.

Unfinished Business

Billboard messages promoting vaccination – Ms. Puluso stated that messages promoting vaccination were displayed on the billboard on Route 46 West near the Home Depot, and also on the electronic sign in front of Town Hall. Dr. Kayne commented that in addition to the Billboard on Route 46 West near the Home Depot, the same message was displayed on billboards near Wood Stack Pizza on Route 46, and on the electronic signs in front of the three Fire Departments in the Township. Ms. Puluso thanked Dr. Kayne for the update.

Reports

Ms. Puluso stated all documents on the agenda were posted to the Montville Township Board of Health page for the Board of Health and the public's review.

Ms. Puluso presented the March 2021 Health Department's Monthly Activity Report and asked if there were any questions. There were no questions.

Ms. Puluso presented the COVID-19 Summary as of April 7, 2021. Ms. Puluso asked if there were any questions. There were no questions. Ms. Puluso noted that the number of deaths due to COVID-19 is now included on this monthly summary to the Board of Health, as that data is now being published by the State on their COVID-19 Dashboard for all municipalities with a population of 20,000 or higher.

Correspondence

None.

Adjournment

Mr. Perry asked if there was any further business to come before the Board.

There was no further business.

MOTION: There being no further business to come before the Board, a motion was made by Mr. Perry, seconded by Dr. Sunil Shah. Ms. Rizzo took a roll call of members present – all in favor, motion passed. The meeting was adjourned 8:46 pm.