



AUDIT COMMITTEE
MEETING AGENDA

September 13th, 2017

1:00 P.M.

125 Worth Street,
Rm. 532
5th Floor Board Room

CALL TO ORDER

- Adoption of Minutes June 13, 2017

Ms. Emily A. Youssouf

INFORMATION ITEMS

- Audits Update
- Compliance Update

Mr. Chris A. Telano

Mr. Wayne McNulty

EXECUTIVE SESSION

OLD BUSINESS

NEW BUSINESS

ADJOURNMENT

MINUTES

AUDIT COMMITTEE

MEETING DATE: June 13, 2017

TIME: 1:00 PM

COMMITTEE MEMBERS

Emily Youssouf, Chair

Stanley Brezenoff

Josephine Bolus, RN

Mark Page

Gordon Campbell

STAFF ATTENDEES

Salvatore J. Russo, General Counsel, Legal Affairs

Colicia Hercules, Chief of Staff, Chairman's Office

Patricia Lockhart, Secretary to the Corporation, Chairman's Office

PV Anantharam, Senior Vice President/Corporate Chief Financial Officer

Paul Albertson, Vice President, Supply Chain

Jay Weinman, Corporate Comptroller

James Linhart, Deputy Corporate Comptroller

Wayne McNulty, Corporate Compliance Officer/Senior Assistant Vice President

Elizabeth Guzman, Assistant Vice President, ERP Finance

Nelson Conde, Senior Director, Affiliations

L. R. Tulloch, Senior Director, Office of Facilities Development

Paulene Lok, Senior Director, Finance

Alice Berkowitz, Assistant Director, Finance

Imah Jones, Senior Director, Research Administration

Donald Ashkenase, Finance, Strategic Advisor

Christopher A. Telano, Chief Internal Auditor/Senior Assistant Vice President

Devon Wilson, Senior Director, Office of Internal Audits

Delores, Rahman, Director, Office of Internal Audits

Rosemarie Thomas, Assistant Director, Office of Internal Audits

Carlotta Duran, Assistant Director, Office of Internal Audits

Frank Zanghi, Audit Manager, Office of Internal Audits

Sonja Aborisade, Audit Manager, Office of Internal Audits

Melissa Bernaudo, Audit Manager, Office of Internal Audits

Armel Sejour, Senior Auditor, Office of Internal Audits

Roshney Kaur, Staff Auditor, Office of Internal Audits

Erica Nairne-Hamilton, Staff Auditor, Office of Internal Audits

Jessica Fortes, Staff Auditor, Office of Internal Audits

Peter Papadopoulos, Staff Auditor, Office of Internal Audits

Erika Soiman, Chief Financial Officer, H + H/Woodhull

Kim Walcot, Coordinating Manager, H + H/Coney Island

OTHER ATTENDEES

PAGNY: Reginald Odom, Chief Human Resources Officer

**JUNE 13, 2017
AUDIT COMMITTEE MEETING
MINUTES**

An Audit Committee meeting was held on Tuesday, June 13, 2017. The meeting was called to order at 1:22 P.M. by Ms. Emily Youssouf, Committee Chair. Ms. Youssouf then asked for a motion to adopt the minutes of the Audit Committee meeting held on April 4, 2017. A motion was made and seconded with all in favor to adopt the minutes. An additional motion was made and seconded to hold an Executive Session of the Audit Committee to discuss matters of personnel and potential litigation.

Ms. Youssouf then said that I'm going to turn it over to KPMG. If you would first as usual introduce your colleagues, and we'll go through your audit plan.

Ms. Tiso introduced herself and colleagues as follows: Maria Tiso, Lead Audit Partner; Joe Bukzin, Team Manager and Mike Breen, Supporting Partner.

Ms. Tiso stated that I'd like to start the Committee off with our audit scope. These are the deliverables that we'll be issuing as part of our 2017 audit. We will be issuing four financial statement opinions, one on the Corporation's audit, the MetroPlus Health Plan, HHC Insurance Company and the HHC ACO. These financial statement deliverables are consistent to what we issued in the prior year.

We will also be issuing a management letter to the Audit Committee on various cost reports for the diagnostic and treatment centers and the skilled nursing facilities, an annual debt compliance letter, and then this year we'll also be issuing a completeness and accuracy census data attestation on the pension deliverable. We have to do this every three years, so this is the third year that we will have to be doing this.

We will be discussing the financial reporting frame work that we perform. The auditing is in accordance with US GAAP as well as Governmental Accounting Standards Board, and the applicable auditing standards are on US Generally Accepted Auditing Standards as well as Government Auditing Standards.

With our client service team, we depicted it a little bit differently this year. This is the core engagement team that's been consistent since the prior year. As mentioned at prior meetings, we also used subject matter professionals as part of our audit, and we will be using those individuals as it relates to tax, actuary and IT professionals. We also do use the minority business firm BCA Watson Rice, so they will be helping us through the audit as well as Healthcare Management Solutions staff, a women's business enterprise. Then we have other partners. Mr. Jim Martell will be joining us probably at the year-end Audit Committee as a healthcare resource. We have a concurring review partner that reviews the financial statements, and then we have another second partner reviewer for the MetroPlus and HHC Insurance.

Ms. Tiso said that I'm going to turn it over to Mr. Bukzin who is going to walk through our audit time line as well as materiality.

Mr. Bukzin saluted everyone and stated that materiality does require us to exercise professional judgment in this area. It's not an exact science. We do look at both quantitative metrics as well as qualitative factors, and we do also consider who the users of the financial statements are.

We've already started our planning process in terms of meeting with management and also having some of our own internal planning discussions amongst our team members to develop the audit plan, which we're presenting today.

This month and next month, we start spending some time visiting the locations, doing some detailed level test work and also working through management in terms of any non-routine transactions or events that we should consider as part of the audit process.

The year-end phase of field work, which begins in the early part of August and runs to the time which we will be issuing our opinion on the financial statements and reporting back to this Committee in December that is consistent with the prior year in terms of reporting on the Management Letter and the results of the audit.

This presentation covers some of the other deliverables in terms of MetroPlus, various cost reports and the insurance company. Those all occur for the most part at the end of 2017 and throughout 2018 with some timing to be worked out as it relates to the ACO for the 2016 and 2017 audit of that entity.

This presentation also touches upon some of the areas in which we will be working with others as part of the audit. We do have subcontractors as Ms. Tiso mentioned before. We've highlighted those areas in which those individuals will be assessing us.

Mr. Bukzin reported that we will not be assigned an internal auditor to assist us, and we did discuss that with the management team. He then turned the presentation over to Mr. Breen.

Mr. Breen began with the objectives of an audit. The objective is to express an opinion on the financial statements, that they're in accordance with generally accepted accounting principles with reasonable assurance. Essentially when you think about what's involved in an audit, it's testing the underlying accounting records. It's also looking at the accounting policies that management selects. It's looking at management's judgments on estimates, and it's also making sure the financial statements are properly presented.

When we talk about responsibilities, we mean management responsibilities. Those statements where we express our opinion, management is responsible for a fair presentation of those statements in accordance with generally accepted accounting principles. Management is also responsible for internal controls, design, implementation and maintenance of controls that would prevent a material misstatement to those financial statements. The Audit Committee responsibility is more over sight, so it's over sight of management and event reporting as well as the internal control environment.

KPMG is responsible to conduct our audit in accordance with professional standards. In the Corporation's case, it's the AICPA or the American Institute of Certified Public Accountants, and then we form and express an opinion whether those financial statements are in accordance with generally accepted accounting principles.

Mr. Bukzin stated that I just want to highlight some of our risk assessment focus areas. These are fairly consistent with the prior year as well. It has to do with evaluation of hospital patient accounts receivable, evaluating the accuracy of the research associated with the flexibility on those receivables. We do use a data analytics tool as part of our independent testing of that area, and with respect to the other two areas, we do have some expertise and subject matter professionals that assist us in those areas, including actuarial professionals.

The other areas which includes other than what was discussed previously, pension, post-retirement, rather large liabilities that are reported on the books and records with balances derived by an actuary report. The actuary assists management with that process, and we review the inputs into that as well.

Some of the other audit areas are routine in nature, but still a focus point, patient revenue streams, related party transactions with the City and also involving our IT professionals with the audit. We identified a couple of items that are on the horizon or that we are going to navigate through with the management team, whether it relates to DSRIP, changing in staff positions and new accounting standards that the City is planning to have the Corporation adopt.

Mr. Campbell asked how extensive is your work in terms of risk assessment and your effort on the auditing and who comprises that team around IT?

Mr. Bukzin answered that we do involve IT professionals as part of the audit, and that does look at changes to the systems. Now, if it's a system change that is not impacting this current fiscal year, they would not be part of the audit scope, so I know there is a go-live in July, which will be next year's focus, so that will be something that would be part of a change in scope for next year's audit where we would focus some attention on that particular project.

From a risk assessment perspective, we do a lot of detail testing as well because information that's produced by the organization, whether it's system generated reports, there's a couple of things that are really important from that perspective. One is are they complete and is the information presented accurate. So we do perform a number of procedures to get comfortable with the information that's coming out of the IT systems.

Mr. Campbell requested that it would be helpful when you are presenting the audit letter in December if you could really drill down on that because my sense is we should be doing more rather than less in this area, so I really would encourage you to give it your all, and I would like to have a detail.

Ms. Youssouf stated that I think we should. That is something we would bring up for next year.

Ms. Tiso reported that another area that we look at every year is liquidity. The auditors are responsible to evaluate if there's a substantial doubt about the entity's ability to continue as a going concern. Some of the liquidity considerations we look at, income loss from operations, various trends that occurred over the past several years. We'll look at working capital trends. We'll look at net deficit position, compliance with debt covenant. So we will be doing our preliminary assessment of liquidity when we receive the March 31st internal financial statements.

Some of the information that we will most likely be requesting from management as we go through the audit, looking at fiscal 2018 budgets and cash flow projections, getting written representations from management regarding ongoing plans, looking at the Transforming Health + Hospitals report, also looking at the 2017 budget as it relates to the current actual results.

As part of our audit, we are required to do the SAS 99 inquiries, and what that is, is inquiries as it relates to fraudulent financial statement audits. These are the individuals. There will be others too that are probably not listed on here that we'll have meetings with to discuss fraud.

KPMG's independence as it relates to the Corporation, we have various checks and balances to make sure that we are independent, so this a list of the policies and procedures that we have to enhance our independence.

- Pre-approval of all worldwide engagements by the audit engagement team through Sentinel, a KPMG independence and conflict checking system (includes services for/relationships with the audit client, its affiliates, and its affiliated persons).
- Tracking partner rotation requirements using PRS, the firm's automated partner rotation tracking system.
- Automated investment tracking system used by all KPMG member firms (KICS).
- Training and awareness programs, including a required annual independence training deployed globally.
- Annual independence confirmation required for all partners and employees and for all new joiners to the firm.

- Compliance testing programs.
- Formal disciplinary policy and process.
- Annual reporting to the Audit Committee regarding independence.

These are the resources that are available to the Audit Committee as it relates to the audit, various committee insights and quarterly reports that KPMG puts out that are available to the Audit Committee members.

- www.kpmg.com/aci
- Publications of the ACI
- Audit Committee insights: www.kpmginsights.com
- Audit Committee quarterly: <http://www.kpmg.com/aci/quarterly.htm>
- Audit Committee institute roundtables: www.kpmg.com/aci/roundtables.htm
- ACI Website: www.kpmg.com/aci
- ACI mailbox: auditcommittee@kpmg.com
- ACI hotline: 1-877-KPMG-ACI
- Healthcare publications
- KPMG insiders, Healthcare: www.kpmginsiders.com
- Healthcare business briefing

Lastly, these are the new accounting pronouncements that we'll be working through with Mr. Anantharam and Mr. Weinman during the year to see the impact that they have on the financial statements. They've already I think met with the City of New York to see which items that they'll be adopting early, so we need to be consistent with the City of New York, and we've already had this conversation as well.

GASB 75, Accounting and Financial Reporting for Postemployment Benefits Other Than Pensions

— Effective for reporting periods beginning after June 15, 2017.

GASB 80, Blending Requirements for Certain Component Units: An amendment of GASB Statement No. 14

— Effective for reporting periods beginning after June 15, 2016.

GASB 82, Pension Issues: An amendment of GASB Statements No. 67, No. 68, and No. 73

— Effective for reporting periods beginning after June 15, 2016.

GASB 85, Omnibus 2017

— Effective for reporting periods beginning after June 15, 2017.

Mr. Tiso then announced that that concluded our audit plan.

Ms. Youssouf thanked them and turned the meeting over to Mr. Telano for the Internal Audits update.

Mr. Telano saluted everyone and reported that I will start the briefing with a summary of the audit that the New York City Comptroller's Office is currently conducting of the Electronic Medical Record System (EPIC). This audit began in September 2016, and they informed us that they plan on completing the fieldwork by September 2017, and then a report will follow, so that audit is ongoing.

Next, this is an audit by the State Comptroller's Office of Nurses' Qualifications. This appears to be a corporate-wide audit as they have gone to Corporate Human Resources, Bellevue, Home Health Care Agency, and they're planning on going to Kings County later this week. They are doing testing and reviewing of nurses' Human Resources files.

Mrs. Bolus asked if there's any reason for the request for Nurses' Qualifications Audit.

Mr. Telano responded no, they did not. We did ask.

Mr. Russo added that we did, they took the fifth.

Moving on to the completed audits, the first audit that will be discussed, is the audit of Corporate Payroll. He asked for the appropriate individuals to approach the table and introduce themselves, they did follows: Elizabeth Guzman, Assistant Vice President, Payroll and Accounts Payable; Mr. John Yan, Senior Director, Payroll; Mr. Weinman, Corporate Comptroller.

Mr. Telano stated that I will go through the findings first, and then you can respond to them. The first issue notes that the Payroll Department is utilizing two different bank accounts to process the payroll since 2003 and as of October 2016 there was a bank reconciliation difference of over \$857,000. This amount would have been higher if not for adjustments made in 2011. We recommended that these two accounts be closed and be replaced by a single bank account, and then once the activity and transactions of the two accounts come to an end, the differences can be written off, and then after the first month of the new account any differences would be easily researchable .

The payroll system does not require additions to employee wages to be approved within that system. Currently there's a form in which approval is indicated; however, there's no verification within the system that the amount on the form was the amount that was actually processed, and there is no required approval within that system.

The processing of payroll is not always done timely or efficient. We noted during the first ten months of 2016, there were over 1600 timesheets with unresolved errors due to coding and scanning issues. We reviewed 24 time sheets with errors and revealed that 20 of them were not resolved timely. Also we reviewed 24 timesheets that were not submitted and found that the requests for those timesheets was also not done timely.

Ms. Youssouf asked how you are planning to or have addressed these issues.

Mr. Weinman stated first I just want to thank Internal Audits for bringing up some of these issues because there were two banking issues in the findings, and I think this is important, and I'll address those, then I'll turn it over to Ms. Guzman for the operations.

The first one is the two accounts. We set up two accounts many years ago to prevent fraud. This way it's hard to determine which bank account we were writing the checks from. Since we have Positive Pay, a system that the bank gets a list from us of all the checks that are distributed, that is the fraud prevention measure that we have in place, and because of it there's really no need for the two bank accounts. I thank you for pointing that out. We're eliminating one account. In fact we have not used it since May, and we will run it out for about six months until we can close it or we reconcile it. The other account that has the smaller balance will remain open, and we will continue to reconcile it.

The other issue is on lack of signatures. There were three checks that were presented by employees that were returned because they did not have signatures on them, so it was pretty embarrassing. We could not figure out exactly what the issue was. We already review every 25th check, and we moved it to every 20th check just to check that all the signatures were there. What we found out from the bank just recently was that the tricolored stamp that we use, has three colors, sometimes it's not picked up by certain scanners, so what happens is when the tricolor stamp is used and it runs through ATM machines, they most likely won't be able to scan them properly. What we've done with investigations both from Deloitte consultants that we have for the ERP system and JPMorgan is that because we have the Positive Pay already in place, we probably don't need the tricolored stamp anymore, so we are going to move to

just black ink. That should save us money, it should save us time and certainly will prevent -- we hope it will prevent some of these scanning errors. The City also does the same thing.

Ms. Guzman stated that the last issue that Mr. Telano mentioned is the processing of time sheets. That is kind of also the nature of the beast. The process of scanning and processing timesheets is labor intensive, but what we are doing is that we did create kind of a higher - level report through IT that kind of lets us know how many errors we have that need to be processed, how many timesheets are missing so we get a sense of what the backlog is. We manage it better, so those reports are starting to come out. There is also the calendar year that closed in April. Typically what happens there is a rush to kind of close the year. Timesheets are coming in, and then it kind of ebbs and flows, drops and then goes up again, but we are just going to have to manage it as best we can in terms of really having a process in place and just looking at what is out there much more regularly to ensure that when there is a backlog we are kind of trying to focus on it to address it.

Ms. Youssouf asked didn't we talk about something else on the way for timesheets?

Mr. Anantharam answered that we discussed the idea of electronic capture of time records so that we don't have as many scanner errors. There currently is a system wide process of actually having the employee log in at the supervisor's desk. We are still looking at it, but it appears there may be a hitch in allowing people to do electronic time keeping on a regular basis. Some of the titles like group 11, that's possible, but we are still investigating it. We have to look at labor practices across the System to figure out whether it is something that can be established across.

Ms. Youssouf commented that again, as we had discussed, it would be a relatively simple fix and that as other people said that they get on a computer and fill out requests for vacation and we are dragging our feet on it.

Mr. Anantharam stated that I don't disagree at all. I just want to make sure that we are not contravening existing policies and procedures, and the only issue there is about line staff who have to register their attendance in the beginning of the day and at the end of the day at their supervisor's desk. If we can find a way to affirm that positively, then we definitely should note that. The idea in ERP is essentially to have a biometric print that establishes a time of entry, and that can happen anywhere in the system. The current practice seems to be a signing at the supervisor's desk, so depending on how prevalent that is, we might have to figure out work arounds on it, but we are looking into it.

Ms. Guzman added that just to be clear though, the errors are like one percent of the problem, less than one percent. The larger issue is just getting the time sheets processed.

Ms. Youssouf added that yes. That's what we were trying to alleviate, so you'll keep us posted on that.

Mr. Anantharam said absolutely, it's clearly an intention across the System. Everybody wants to get to a place where there are a lot fewer of these errors. That's the only one box that we need to check off.

Mr. Telano continued with the briefing stating that this was an audit of the Pharmacy Department at McKinney. Will the representatives from McKinney please come to the table and introduce yourselves please. They did as follows: David Weinstein, CEO; Christos Kouretsos, Pharmacy Director and Charmaine Lewis, Deputy Executive Director.

The first issue has to do with the management and the security over the pharmacy inventory. We did a count during the audit and found a 50 percent error rate mostly due to the lack of timely updating of the inventory system.

Second, we found that the names of individuals with possession of keys and the quantity of keys distributed for access to the pharmacy medication rooms and narcotic cabinets are not tracked by the facility's management department.

We also noted there were no cameras to monitor the movement of medication within the McKinney Pharmacy Department.

Moving on, we noted that the pharmacy director and one pharmacy technician both have eCommerce access to purchase and receive pharmaceutical items. In addition, the pharmacy director had the ability to adjust inventory, and the technician could approve purchases. So in summary the technician could approve, purchase, and receive pharmaceutical items.

We also found that four individuals outside of the Pharmacy Department and one Central Office employee had access to the pharmacy system. We also noted that the system, QS 1, is not robust enough to use as an analytical tool. Though the system does generate billing reports, it does not provide information to trend the number of claims denied or the number appealed or over turned. We found 19 Accounts Payable credit memos from 2014 totaling \$21,000 that were not processed. Lastly we found that the ordering of narcotics were not done through the system. Instead they were done manually by filling out a form, which basically resulted in the ordering being extended.

Ms. Youssouf asked could you please address these, what you are doing or have done, please.

Mr. Kouretsos reported that the first one, the inventory discrepancies, is under the review of eCommerce. The eCommerce team had to retrain our staff and reset all the priorities for the individuals required to do the various functions that were needed there. That was done on the 21st of April and the 8th of April, the 5th of May and the 17th of May under the review of Mr. Hector Ramirez, the eCommerce administrator, so that's the actual inventory discrepancies. The inventory discrepancies were due to untimely removal of stock from the stores. Due to a staffing situation, that has been improved.

The physical security has been amended to show cameras inside the pharmacy and outside the pharmacy, and the Director of Security at Kings County Mr. Juan Checo was in charge and did that. I have memos showing that cameras are live in the facility and feeding live stream to the main feed at Kings County.

Ms. Youssouf asked if there is some kind of check with the inventory against the cameras of who goes in and takes stuff out, or is there some way of cross-referencing that.

Mr. Kouretsos continued and stated that the process used by eCommerce is a tickler system, a list. Then that list is given to the person to review those. As far as the cameras, there were never cameras that were placed in the facility. We're not talking about a pharmacy with different rooms. We're talking about a pharmacy that only has one room, a direct and indirect view of a pharmacy.

Mrs. Bolus asked if there were no camera. To which Mr. Kouretsos answered that there is cameras now. There were no cameras before.

Ms. Youssouf asked if someone is looking at what the camera is capturing.

Mr. Kouretsos responded that there is live feed, and then there's a 30-day feedback at Kings County.

Mr. Kouretsos stated that regarding security issues, there are presently four pharmacists including myself, one pharmacist is on FMLA. So there are three keys. I have a key, my two pharmacists have a key. The remaining key is locked up in the pharmacy vault. As far as the keys in the box upstairs, the only one who has access to that is the nurse managers, and they have the keys are passed off at each shift change. Any change in keys or locks or cylinders are in my possession, and upon my request, those keys are changed out with supervision of myself and the Director of Building Services. Nobody else has the keys. Nobody has access.

Security access, there are once again the only ones allowed to change or enter such information are the pharmacists. In May 2016 there was a fire wall thrown up by the QS1 people as per New York State regulations. Anything after that time, no one was allowed to cross that fire wall without knowing the passwords. Earlier this year I had thrown up a second firewall, a change of passwords. Those are being changed as we speak, and I have a listing of all individuals who have access, granting of access as of June 1, 2017.

Management over sight of denials of pharmacy claim, a tele-conference and a meeting will be held with QS1. QS1 has trained the pharmacy staff not only at McKinney, but the other four SNF's to use the QS1 system, and we are at this time using best practices.

To go above and beyond that, I have since requested an interview with QS1 and on site meetings with QS1 to say what else can be done in order to catch any and all receivables that may be left on the table. That meeting will occur in two weeks with my presence, and a little help from the shifts, and if I do it correctly, I will train the other shift directors in best practice moving forward. With thanks to Mr. Telano, our unused credits are down to \$1,140. All credits are being applied accordingly and in good time and good order, and hopefully we will continue that way. We do not want to have \$20,000, \$30,000 left on the table.

Manual ordering of narcotics -- the standard format used by the pharmacy is a class 222 form, which is signed only by myself and authorized only by myself. There's an eight-step process required in order to change over switching into a CSOS system, which is ordering of controlled substances through computer access. It must be used only by one computer, only by one vendor, only by one person and only by one access number. That will go to process in coordination with Cardinal, QS1 and the DEA people in order to do that. Hopefully I'll get access to that, and then I'll have to get the backup pharmacist to do that. My backup plan is to use the 222 forms if process is not available or and if the system does go down, and eCommerce does go down from time to time.

Ms. Youssouf recommended to Chris Telano, that I think putting together what is the best practice for all of these would be really helpful because in the past issues similar to this have come up at other facilities. And obviously get copies to the Committee, but most importantly make sure to document that it is been sent to every facility so there's no ambiguity about what they should and should not be doing.

Mr. Campbell added that I just want to second Ms. Youssouf because I was thinking the exact same thing. Actually, it would be great for you to come back and report how you plan to cascade this throughout our acute-care hospitals as well ambulatory settings because I'd be surprised if there were not challenges similar in other facilities. If we can get a report back, that would go a long way.

Mrs. Bolus asked if the facility is still using the paper? To which Mr. Telano answered no. This is the first audit that was done at one of the nursing homes of the pharmacy department.

Mr. Telano moved onto the next audit, Temporary Nursing at Queens. He asked for the representatives to approach the table and introduce themselves. They did as follows: Chris Roker, CEO; Joan Gabriele, Chief Nursing Officer; Hedy Wang, Nursing Administration and Peter Maris, Director of Human Resources.

Mr. Telano stated that I'll go through the findings real quick.

First our review of invoices revealed 15 Agency Sign-In Logs could not be provided. We believe it was due to record-retention issues.

Second, we found 5 terminated employees that still had access to Epic. The HR Department did send e-mails to the EITS Department requesting them to be removed, but it was not processed.

Third, the nursing scheduling process is repetitive and time consuming. The scheduling system, ANSOS, is a three-step manual process that takes six weeks to complete.

Fourth, in looking at the scheduling system and looking at who has access in comparing it to the forms that are filled out upon request, we found the following discrepancies:

- 40 users' request forms did not match the Access Report's user roles and authority levels.
- 13 individuals, for whom request forms were completed, were not found in the ANSOS Users' Access Report.
- The User Access Report reflects active access for 3 individuals who are no longer required to access ANSOS, due to changes in their job duties or termination.
- 22 request forms were improperly signed off by the Requestor, instead of the required Department Head.
- 13 users' request forms were not retained and could not be verified.
- Two different ANSOS Access Request Forms were being used to request access, which creates confusion and errors when access is being granted.

Lastly, the personnel files for the temporary agency nurses were lacking relevant background check documents.

Ms. Youssouf asked could you please tell us how you addressed these or are planning to.

Ms. Gabriele responded that with regard to missing Agency Sign-In Logs, we accepted the findings and we now have a process in place to maintain the records for six years as required, and we are monitoring that and are in compliance.

Ms. Youssouf asked if you are retaining physically.

Ms. Wang answered that physically. Also we are going to scan into a shared drive, so everybody who is handling the agency access will be scanning those sign-in sheets to the shared drive.

Ms. Gabriele added that with regard to inaccurate access report, we have removed, reconciled any access users who are no longer part of the employ or used in our facility. We have reconciled all of that, and in the future obviously, we will monitor and make sure that our security access is accurate and maintained.

Mr. Guido reported that about 18 months ago, we brought up a project to consolidate all access levels throughout the organization. There were 24 different access points in, and it was managed from a federated standpoint. We have consolidated all 24 to one, so that has been completed. We also have made sure that every employee has to be in PeopleSoft now, so everybody is in there. If they are not in PeopleSoft, they will not get access to our systems, so that has been completed as well. We have put a process in place for the whole organization that tickets have to be submitted in order for us to take resources off. It's more of a training thing that we're going through once again to make sure everyone understands what the new process is moving forward.

Beginning of July we will have automated removal of resources. Once they are disconnected from the Corporation, they will be taken out of PeopleSoft. That will automatically remove all access to every one of our systems, so as we had stated about 18 months ago, we are on target.

Ms. Youssouf asked if that is system-wide.

Mr. Guide answered that that is system-wide for every system that we have in place and all security and also mobile access levels as well, so starting July we should be in very good shape that this is all automated. Our affiliates as well

have access to PeopleSoft now. They are required now to take anybody out of PeopleSoft once they disconnect from our organization.

Mrs. Bolus asked if it's automatic. To which Mr. Guido responded that it will be automatic starting in July, so again we had a lot of work to do. We had to consolidate a lot of different access points.

Ms. Gabriele stated that in terms of improper record keeping and retention of documents, our agencies are required to keep these documents, We now have immediate access to these documents electronically through Vizient, and we are copying these documents and putting them in our files and maintaining a much better order to the file as was recommended by the auditors, so these documents are on site for immediate review if required.

Mr. Telano continued with the audit of affiliate operations of the Physician Affiliate Group of York City Health + Hospitals/Harlem. Will the appropriate individuals please come to the table? Introduce your selves, please: Luis Marcos, CEO; Reggie Odom, Chief HR Officer and Rob McKenna, Chief Affiliation Officer.

Mr. Telano reported that a review of 38 payments to contractors revealed that six invoices were paid in full although the providers did not complete the number of hours required by their contract. For example they were being paid eight hours although they only worked four hours, and some individuals working three and paid for four and in some instances paid for four and did not work at all.

As required by the contract, schedules are to be maintained by the various clinical departments in order to verify the hours worked, and the individuals were actually there. They are supposed to use these schedules to compare to the timesheets. However, they were not being maintained properly.

Moving on, this has to do once again with system access, and for the most part we see that Human Resources and PAGNY did send email notifications out to the appropriate parties, and once again EITS did not process it.

Last, regarding the recalculation process, it is not effective as it is completed in four different separate steps, and we recommended that it be more condensed and some of these steps be done at the same time.

Dr. Marcus said that we would like to address each of these findings. I mean to err is human, but that does not mean that we accept mistakes, and we welcome any suggestions for improvement, but I think it is important for us to address each one because things are a little bit more complicated than they sound. Let's start with the hours, and I will ask Reggie Odom and Rob McKenna to expand on that.

This finding applies to four physicians that work. We have a contract with Columbia University, and not only -- let's address first the issue of the time.

Mr. Odom reported that we have contracts with Columbia to provide support. One of the things that PAGNY did in response I think to a prior audit finding maybe a year or two ago is we made some adjustments to our standard contract to define that session that somebody provides support in to be a four-hour block. We were trying to be more precise about the time. One of the errors we made there was sometimes when we were engaging sub specialists and unique skill sets that we need, they don't necessarily always have a full panel of people to see during that four-hour block, so if you are doing a clinic related to sickle cell for example, maybe in that particular instance there's not enough patients. In that case the person may have only worked three hours, so we need to kind of go back to those contracts and redefine that and make sure it's clear in each of the instances.

Mrs. Bolus commented that I'm not so sure we are going to get the correct amount of people actually staying and not walking out the door a little bit earlier by doing that because at least we had them on a time frame and we knew to

look for them so if a patient was coming in at the three-hour time, and the doctor decided that two hours and something he's seen everybody he wants to see and goes home. That patient coming in at three hours, he's not going to be seen by a specialist.

Mr. Odom stated that that's not really the issue. In these particular specialty clinics, they're appointment-based, and we don't really have walk-ins.

Mrs. Bolus added that you may not have walk-ins, but if you know the doctor's going to be there from 8:00 to 12 noon and you're having problems, especially sickle cell, and you're having a crisis and you're having difficulty getting there, and you just get there and he's walked out the door five minutes before because he didn't stay within that limit of time, then the patient is the one who's lost, and that's what I disagree with. That's why I disagree with the flexibility you put into this scheduling. The way you've written it, he can say I think I have seen everybody today and it's close to my time to leave, I'm going to leave, and he'll do so, and the patient will suffer.

Dr. Marcus commented that I think you are making a very good point. We have not had a situation where a patient was not seen because of this.

Mrs. Bolus added that that it's a possibility.

Dr. Marcus agreed that it is a possibility. This arrangement gets a little bit more complicated because these physicians give Harlem additional services that they don't charge us for. I'm saying this because I paid them by session even though in some cases they don't work the full four hours, the understanding is that these physicians have on-call time at home, and they don't charge us for that and other services.

Mr. McKenna reported that there are some services that Harlem asked them to do subsequent to the signing of the agreement. One of the major ones in this case pediatric surgery, which is a subspecialty, required backup calls be identified this year. So ADV Pediatric Surgery, which is the subcontractor in this place, just agreed to do that subservice, so there are times when we get additional services. We also utilize the chief of ADV Pediatric Surgery to be the chief of trauma at Harlem Hospital at no additional charge to the hospital so we believe that we are getting good value from these contracts besides the actual charge in the scope of services that we actually documented.

Mrs. Bolus asked do you have the documentation to show anything about whether this is a good deal or not. There's really no way to know? How do we know that we are getting the good end of the stick rather than the doctor?

Mr. McKenna answered that well, I'll tell you that for the best that we have done, and I think it's pretty adequate, we get a scope of services, which is very, very detailed, and it's very difficult because we often use small FTEs of these subcontracts. For example, somebody who is an HIV specialist for pediatrics. So the Columbia group presents what they feel should give you, and then the H + H lawyers argue back, and we go back until we get a compromise, and that is priced according to what both parties ultimately end up on, so we have quite a bit of push back from H + H to defend the hospital as well.

Ms. Youssouf asked do we have a contract that works a little more efficiently than these outstanding with others.

Mr. Telano responded yes, the majority of the contracts are all written that they just get paid the number of hours worked.

Ms. Youssouf suggested that if you could please give them a copy of the contracts which you believe are working properly and have it built in because you said there's some issue with how they have been written in the past. Perhaps it would be helpful to them. Can you be sure you do that?

Mr. Russo answered yes.

Ms. Youssouf stated that as far as employee access goes, I think we know what's going on with that. Is it the same thing?

Mr. Guido stated that it's the exact same thing, so we've made this enterprise-wide for anybody coming into our facility to work, so it's the exact same thing as we had previously talked about.

Ms. Youssouf said that the next thing is the recalc problem, which I know has been an issue. Fiscal year '15 is not completed yet. What is the continuing issue with that? Because I know you've tried a number of ways to have that work better.

Dr. Marcos responded that as you know it takes at least four different individuals or entities to finalize recalc. One of them is PAGNY, and the three others are different Health + Hospitals level, the hospital, Central Office, Finance, and I would like Mr. McKenna to share with the Committee in this particular case what seems to be the problem.

Mr. McKenna reported that in all the years I have been through the recalc process, and I used to work for Columbia, this is the best year by far in terms of the process that's in place. We just came down to one issue, and the issue really regards an interpretation of a policy that's in the contract. We feel it should be interpreted one way, and the facility sides with us, and H + H Finance believes it should be interpreted a different way, so it's down to that one issue. When we resolve that one issue, we will actually be able to execute both.

The issue is that at the beginning of the year, we try to H + H and PAGNY execute an affiliation agreement, and they decided upfront how much of the cost of the physicians should be borne by the physicians themselves for their own faculty practice, and it's generally about 20 percent. Every year, at the end of year, we look to see if there's adjustments. The adjustments could be that if H + H gave a million dollars to the contract during the year, we would want to raise the what we call the carve out of the amount of that they should pay for, that the physicians should pay for, so that H + H gets some benefit from it. What we are finding is we really were not getting a lot of new money. We were moving money throughout the budget, so we moved from one department to another and back, and what happened was if you look at the contract, in my interpretation, you take money and you move it to another department, there really should be no impact on the overall carve out. It's plus one, minus one. That's the way most of us feel. The Finance Department felt that that movement should be shown as an addition to the carve out but not a subtraction from the originating department unless we were able to have provide certain circumstances.

Ms. Youssouf stated that so that's it. It's a disagreement about it. Could I ask, PV, if you could find somebody who could look into it?

Mr. Anantharam responded that I think we need to dig a little bit deeper to understand. The FPP agreement across the System vary from facility to facility, and I concur wholeheartedly that process of reconciliation is a way to prolong and delay and does not serve anybody well, so we have to find something, so I will definitely go back and look at this particular item.

Mrs. Bolus stated that Dr. Marcos, I want to thank you because I remember when we first started, this it was a real big confusing mess, and you seem to have brought some light to some portions of it, not all but some portions.

Dr. Marcos said thank you. Thank you for your support.

Mr. Telano stated that that concludes my presentation.

Ms. Youssouf turned the meeting over to Mr. Wayne McNulty, Corporate Compliance Officer.

Mr. McNulty saluted everyone and introduced himself as Wayne McNulty, Senior Assistant Vice President, Chief Corporate Compliance Officer.

For the first quarter of calendar year 2017, we had one privacy incident that resulted in a breach of protected health information. This breach occurred when an individual was allowed to volunteer at Coney Island Hospital without proper HR approval authorization, and that resulted in the access of 3,494 patient information. We sent out a breach notification to those individuals. We also sent out a notice to the Office of Civil Rights of the Department of Health and Human Services, and we sent out a notice to the media with respect to that particular incident.

Moving on to the monitoring of excluded providers, we have no excluded providers noted for the sanction screening for the time period from the last time that the Audit Committee convened. Besides reviewing excluded providers on the OMIG, OIG and SAM exclusion list, we are also reviewing to ensure our employees are not on the Office of Foreign Asset Control, the Department of Treasury list or the Social Security Administration Death Master list.

Moving on to a summary of compliance related reports from the first quarter of calendar year of 2017, we have received 96 reports in that three-month period from January 1st to March 31, 2017. Out of those reports, two were priority A, 41 were priority B and 53 were priority C reports. Priority A reports are the most crucial reports that require immediate attention. Because these matters are under investigation, I'm not going to elaborate any further with respect to those particular reports.

I want to provide a status update to the DSRIP compliance attestation of One City Health partners. We provided in early February each One City Health partner with an attestation so we could assess their compliance program integrity. There were several different items that we wanted to assess. One was we wanted to assess the DSRIP compliance training to ensure that they have trained their personnel. We have provided them with training. They can use their own training or they can use the training that was provided by Health + Hospitals. We also require that they adhere to our Principles of Professional Conduct or they adopt a similar code of conduct that follows the same principles as Health + Hospitals as it relates to standards of conduct.

We also requested proof that they are certified with the Office of the Medicaid Inspector General and that they are also certified with the Office of Medicaid Inspector General for the Deficit Reduction Act and they distribute appropriate policies and procedures on fraud, waste and abuse to their personnel. We also wanted them to confirm that they screen their work force members for sanction screening.

There's an update to the last time we presented this issue to the Audit Committee in April. Out of their 193 DSRIP partners that are eligible to receive DSRIP funds, 170 of the partners have completed the attestation as of June 13th. You'll see 157 in the report, but that was as of June 8th. As of today 170 partners out of the 193 eligible to receive DSRIP funds have completed the attestation, and we are very hopeful that within the next week or two we will have all 193 partners provide us with attestations. We also wanted them to confirm that they screen their work force members for sanction screening.

Lastly, I want to provide a status update with respect to Health + Hospitals compliance with the HIPAA Security Rule Risk Analysis requirements. Back in 2015, February, I reported to the Audit Committee that Health + Hospitals' compliance with the Security Rule of HIPAA as it relates to our evaluation of all pieces of information systems that house, transmit or store electronic protected health information was a work in progress and not comprehensive in that particular juncture. I have also reported that although EITS has provided numerous and significant measures to enhance and maintain confidentiality and integrity and security of Health + Hospitals information system, the formal

risk analysis requirements were not met. I have Sal Guido, who is Senior Vice President, Chief Information Officer, here to provide the Audit Committee with an update of the measures that have been taken by EITS since that February 2015 Audit Committee.

Mr. Guido stated that we work very closely with the Office of Compliance, Mr. McNulty, on the HIPAA Security Risk Assessment for our PHI systems. So we embarked upon this about three years ago, and we selected a third vendor to come in and do an independent audit and risk assessment of our environment, our security and then our PHI applications. They have been performing that over the last three years really focusing on HIPAA privacy, security and breach notifications, configuration review of all of our hardware and applications. We conducted penetration tests both internal and external, the application security review of the 29 applications that have EPHI on it and the vendor risk management of those same 29 vendors.

With that, again, Solutionary comes in and does a comprehensive review on our administrative safe guards. That's security management access controls training and then the BAAs for our partners. There's a physical safeguard associated with that, access to physical facilities, workstations and device and media controls and really the technical safeguards, the access control methods to access to our systems, the audit control and the transmission of this data both internal as well as external. Based on this year's assessment, there are critical, high/medium and how findings that Solutionary provided us. From a critical standpoint there was a 119. Of the 119 there are remediation plans in place for corrective action for 108. I'm not going to read through all of the numbers, but we have made some significant progress in protecting our EPHI from break-ins.

Last, one of the last things that we did, about 12 months ago, there was an audit under taken that showed that there was EPHI in all biometric devices that needed to be managed and removed in a timely manner. From that point we actually have remediated all of Coney Island right now from a biometric standpoint so that EPHI gets automatically removed from the biometric devices and screens. We have been awarded funding to complete the rest of our facilities from the bio metric standpoint, and those are the monitors, the cardios, so we believe that once the POs and the funding is in place, this will all be remediated within a 12-month period of time.

Mrs. Bolus if the whole thing is being paid for by the City, not us?

Mr. Guido answered that this is City funding in the capital plan.

Mr. McNulty announced that if there's no further questions, that concludes the Corporate Compliance report.

Mr. Campbell announced that on the agenda it did show we will go into executive session, but we will actually go into executive session at the Board meeting

There being no other business, the meeting was adjourned at 2:25 PM.



**AUDIT COMMITTEE OF THE
NYC HEALTH + HOSPITALS
BOARD OF DIRECTORS**

Corporate Compliance Report

September 13, 2017

Table of Contents

I. Compliance Review of Institutional Review Board Agreements.....Pages 3-13

II. Summary of Compliance-Related Reports for the Second Quarter of Calendar Year 2017Pages 13-16

III. Monitoring of Excluded ProvidersPages 17-19

IV. Status Update - DSRIP Compliance Attestation of OneCity Health PartnersPages 19-21

I. Compliance Review of Institutional Review Board Authorization Agreements

Overview

- 1) Recently, the Office of Corporate Compliance (“OCC”) conducted a review of all of the NYC Health + Hospitals (the “System”) Institutional Review Board (“IRB”) Authorization Agreements (hereinafter “IRB Authorization Agreement” or “Agreement”) with external IRB’s to determine if the Agreements have the necessary terms and conditions to: (i) meet applicable legal and regulatory requirements; and (ii) mitigate certain risks involved with conducting human subject research at System facilities. Additionally, the OCC reviewed the Agreements to determine if any non-standard IRB service was being provided by the IRB, which would in turn require the IRB to enter into Business Associate Agreement (“BAA”) with the System.
- 2) The paragraphs that follow contain the specific findings related to the OCC’s review and associated recommendations. The Office of Research Administration (“ORA”) was previously provided with a draft of this Report for Management Response which has been included in the Report.
- 3) Before going through the findings, it is important to highlight that the OCC did not find evidence or note any incidents that would indicate harm to any human subject research participant.

Introduction

- 4) By way of background, as part of its review to ensure HIPAA Privacy and Security compliance, the OCC requested that the ORA provide it with all BAAs entered into with external IRBs providing oversight of human subject research conducted at System. A BAA is required when a person or entity, other than a member of the workforce of the System, performs functions or activities on behalf of the System that requires the person or entity to access, disclose, use or transmit protected health information (“PHI”). HIPAA generally requires that covered entities and business associates enter into contracts to ensure that the business associates will appropriately safeguard PHI. A business associate is directly liable under the HIPAA Rules and may use or disclose PHI only as permitted or required by the BAA or as required by law.
- 5) The ORA provided OCC with only one BAA, which was entered into with Biomedical Research Alliance of New York (“BRANY”). The BRANY BAA was expired and therefore did not meet the new BAA requirements set forth under the HIPAA Omnibus rule, which implements the Health Information Technology for Economic and Clinical Health Act (“HITECH”) provisions of the American Recovery and Reinvestment Act (“ARRA”) of 2009. The other nine (9) IRBs with which the System has IRB Authorization Agreements did not have BAAs.
- 6) During its review the OCC also noted that many of the IRB Authorization Agreements were missing key contract provisions and did not have enough information in most cases to

determine if a BAA was required. These preliminary findings necessitated that the OCC review all System IRB Authorization Agreements to determine if they adequately mitigated the System's risks and whether BAAs were required by HIPAA for the external IRBs.

Legal Background

Business Associate Agreement Requirements

7) It is important to note that, generally, IRBs are not considered business associates under HIPAA even when they serve as an external IRB to a covered entity such as the System to perform research review, approval, and continuing oversight. Therefore, the System is not required to enter into a BAA with organizations providing IRB research oversight services on behalf of the System. However, if the IRB goes beyond providing standard IRB research oversight services including, without limitation, billing services or other healthcare operations, a BAA may be required if such services involve the use, access, disclosure, or transmission of protected health information ("PHI").

IRB Authorization Agreement Requirements

- 8) Federal and State regulations¹ mandate that research involving human subjects be:
- reviewed and approved by an IRB; and
 - subject to continuing review by the IRB.²

The IRB is responsible for providing guidance and oversight for the human subject research protection program and for helping to maintain compliance with applicable research laws, regulations, and policies. The IRB reviews the research protocol design and patient consent forms and/or related documents for the scientific soundness of the research project, risks, benefits and any ethical issues relating to the safety and general welfare of the subject.³ Institutions can outsource the responsibilities of an IRB by entering into an IRB Authorization Agreement.

Scope of Review

9) For most of the human subject research conducted throughout the System, the System has outsourced the roles and responsibilities of the IRB to external institutions pursuant to IRB Authorization Agreements. Within the System, there is only one internal IRB which is located at NYC Health + Hospitals/Lincoln. IRB Authorization Agreements are necessary to set forth the respective roles and responsibilities of the IRB and the System. Currently, the System has IRB

¹ 45 CFR Part 46; 21 CFR Part 56; and New York State Public Health Law ("PHL") § 2444.

² 45 CFR § 46.109.

³ 45 CFR § 46.108.

Authorization Agreements with the following external entities, all of which were reviewed by the OCC:

- Albert Einstein College of Medicine;
- Biomedical Research Alliance of New York;
- Maimonides Medical Center;
- Mount Sinai School of Medicine;
- National Cancer Institute;
- New England Institutional Review Board;
- New York Medical College;
- New York University School of Medicine;
- SUNY Downstate Medical Center; and
- Western Institutional Review Board, Inc.

Findings

10) The OCC's review of the foregoing IRB Authorization Agreements found that the majority of the Agreements:

- lacked consistency from a content perspective; and
- omitted key contractual provisions necessary from an internal control perspective to protect the interests of the System and mitigate certain risks inherent with the conduct of human subject research.

A summary of OCC's findings are as follows:

Finding 1

11) Except for the System's Agreement with BRANY, and to a lesser extent, Maimonides, the Agreements reviewed by the OCC did not provide sufficient detail concerning the services being provided by the IRB for the OCC to make a determination whether the IRB needed to sign a BAA with the System. Specifically, 10 NYCRR § 400.4 sets forth minimum standards and general requirements for medical facilities under the New York State Department of Health ("DOH"), and provides that contracts to perform any services for a medical facility should include each party's

“responsibilities, functions, objectives, financial arrangements, and charges.”⁴ In fact, two of the IRB Authorization Agreements (SUNY Downstate and Einstein) were only one page long. And although the Western agreement is 12 pages long, there is only one paragraph that outlines the IRB’s roles and responsibilities as it relates to human subject research oversight.

All of the IRB Authorization agreements should also include the following language: “*Notwithstanding any other provision in this contract, the facility remains responsible for ensuring that any service provided pursuant to this contract complies with all pertinent provisions of Federal, State and local statutes, rules and regulations.*”⁵ Only the BRANY agreement included such language.

Finding 2

12) The majority of agreements were not reviewed by Office of Legal Affairs (“OLA”) as required under Operating Procedure 180-9 (“OP 180-9”) *NYC Health + Hospitals Human Subject Research Protections Program Policies and Procedures*, which was adopted by official resolution by the NYC Health + Hospitals Board of Directors on November 20, 2014 and signed by the President and Chief Executive Officer on April 29, 2015. OP 180-9 requires that all research agreements be reviewed by OLA. Specifically, the OCC found that only the BRANY and Western IRB Authorization Agreements were reviewed and approved as to acceptability as to legal form by the OLA.

Finding 3

13) Many of IRB Authorization Agreements reviewed by the OCC were deficient from an internal control perspective because they lacked key contractual provisions necessary to mitigate certain risks involved with conducting human subject research at System facilities. While several of the IRB Authorization agreements (*e.g.* Mount Sinai, NYU, New England, New York Medical College, National Cancer Institute and Maimonides) have details of the IRB’s roles and responsibilities that are adequate enough to mitigate certain System risks, none of the Agreements, other than BRANY, have the full spectrum of the recommended contract protections necessary to serve as effective internal controls that would mostly likely mitigate corresponding risks to a desirable level from a compliance perspective. The deficiencies found in the various Agreements include, without limitation, the following:

Contract Deficiency 1: IRB Ongoing Registration with Office of Human Research Protections (“OHRP”)

⁴ 10 NYCRR § 400.4

⁵ 10 NYCRR § 400.4 (a)(4)(emphasis added).

14) All of the IRB Authorization Agreements include the IRB institution’s IRB Registration number. However, other than the BRANY Agreement, the IRBs were not contractually required to maintain a duly constituted institutional review board registered with OHRP.

15) Also, since three (3) of the IRB Authorization Agreements (Mount Sinai, New York Medical College, and New England) were executed over nine (9) years ago in 2008, the IRB registration process in place at the time of the effective date of these Agreements has since changed. Further, some of the IRB Registration numbers highlighted in the Agreements are no longer active.

Contract Deficiency 2: IRB Registration with Other Regulators

16) In addition to registration with OHRP, IRB registration is required with the Food and Drug Administration (“FDA”) for IRBs that review:⁶

- clinical investigations regulated by the FDA; or
- clinical investigations that support applications for research or marketing permits for products regulated by the FDA including, without limitation, drugs and medical devices for human use.

17) Further, approval of IRB members by the New York State Department of Health (“DOH”) may also be necessary to the extent required by DOH.

18) Only the BRANY and National Cancer Institute Agreements referenced the relevant FDA human subject research protection regulations, and only the BRANY Agreement specifically required IRB registration with the FDA. Further, only BRANY referenced the aforementioned DOH requirements.

Contract Deficiency 3: Compliance with the Systems’ Federalwide Assurance

19) For research involving human subjects conducted or supported by Department of Health and Human Services (“HHS”) or any U.S. department or agency, the HHS regulations require as part of its human research registration process a written assurance - - referred to as the Federalwide Assurance (“FWA”) - - from the performance-site institution that specifies that the institution will comply with U.S. Federal regulations for the protection of human subjects in research.⁷ A FWA application must be approved by the OHRP, an agency of HHS. NYC Health + Hospitals has a FWA filed with OHRP pursuant to 45 CFR 46.103.

⁶ 21 CFR 56.101 (a); 21 CFR 56.106 (a)

⁷ 45 CFR § 46.103.

20) The Systems' FWA states that all of its activities related to human subject research, regardless of funding source, will comply with the OHRP Terms of the FWA for Protection of Human Subjects and regulations set forth in 45 CFR Part 46 and all of its subparts (A,B,C,D), and all applicable federal policies. The FWA also states that the System elected to be guided by the ethical principles found in the *Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research* (1979) ("Belmont Report").

21) Based on the foregoing, the IRB Authorization Agreements should include the System's FWA terms of assurance and obligations in the Agreement, or include the FWA as an exhibit and incorporate all System responsibilities under the FWA by reference for performance of the same by the IRB. Most of the IRB Authorization Agreements provide that the IRB will meet the human subject research protection requirements of the System's OHRP-approved FWA. However, only the BRANY IRB Authorization Agreement lists in detail what is required of the IRB to meet the terms of the System's FWA and satisfy the obligations of the System under the FWA.

Contract Deficiency 4: Adherence to Belmont Principles

22) The System's FWA states that its activities related to human subject research will be guided by the ethical principles found in the Belmont Report. Only the BRANY Agreement contained language regarding the Belmont Report and Principles.

Contract Deficiency 5: Notice of Unanticipated Problems

23) HHS regulations of human subject research require written procedures for assuring prompt reporting to the IRB, appropriate institution officials and the department or agency head of (i) any unanticipated problems involving risk to subjects or others of any serious or continuing noncompliance with applicable regulations or the requirements or determinations of the IRB; and (ii) any suspension of IRB approval.⁸ Special notice provisions should be included for "serious adverse events."⁹ Most of the IRB Authorization Agreements have some general references to the requirement that the IRB report to the System unanticipated problems involving risks to human research subjects or others. However, consistent with the OHRP guidance, only the BRANY Agreement contains detailed notice provisions that include specific time frames for providing notice of unanticipated problems that are deemed (i) serious adverse events; or (ii) not serious adverse events, which are both defined by differing criteria under OHRP guidance.

⁸ 45 CFR § 46.103(b)(5).

⁹ Unanticipated Problems Involving Risks & Adverse Events Guidance, Office for Human Research Protections, available at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q6>.

Contract Deficiency 6: IRB Knowledge of Local Research Context

24) HHS regulations of human subject research require that each IRB have at least five (5) members with diverse backgrounds including consideration of race, gender and cultural backgrounds and sensitivity to such issues of community attitudes.¹⁰ Institutions have a responsibility to ensure that all IRBs possess sufficient knowledge of the local research context.¹¹ Several of the IRB Authorization Agreements (Mount Sinai, NY Medical College, New England and NYU) state that the System will, upon request, assist the IRB institutions in providing eligible consultants to serve on their IRBs to meet local context requirements. However, only the BRANY and National Cancer Institute IRB Agreements make the IRB specifically responsible for meeting the local context requirements. And with regard to the National Cancer Institution IRB Agreement, the local research context is defined in a manner that might be problematic in assessing its application at the facility level in circumstances where the subject rule applies.

Contract Deficiency 7: Confidentiality of Subject Information/Business Association Agreements

25) IRBs are exempt from the HIPAA Privacy and Security Rules, and therefore, the System is not generally required to enter into a BAA with IRBs. However, if the IRB - - in its role as and IRB or a privacy board - - provides services not related to research review, approval, and continual oversight functions, (e.g., billing services, creating a de-identified or limited data set or other healthcare operations), a BAA may be required if such services involve the use, access, disclosure or transmission of PHI. At the time of the OCC review, only BRANY had signed a BAA with the System. The lack of details in some of the other Agreements make it difficult, if not impossible, to ascertain if non-standard IRB services are being provided, which would require a BAA. Even if a BAA is not required, the following data privacy and security contract provisions should be included in the IRB Authorization Agreement:

- *Permitted Uses and Disclosures of Confidential Subject Information*

Provisions should be included regarding the permitted use and disclosure of confidential subject information by the IRB, including without limitation, disclosure to third parties, use of de-identified data, and use for research purposes.

- *Responsibilities of the Parties with Respect to Confidential Subject Information*

Provisions should be included regarding safeguarding confidential subject information, including without limitation, minimum necessary disclosure, and binding subcontractors and agents to privacy requirements.

¹⁰ 45 CFR § 46.107(a).

¹¹ OHRP Guidance "IRB Knowledge of Local Research Context" dated July 21, 2000, available at: <https://archive.hhs.gov/ohrp/humansubjects/guidance/local.htm>.

- *Applicability of Certain State Confidentiality Laws & Regulations*

Provisions should be included which refer to New York State confidentiality laws (e.g., Public Health Law Article 27-F, as it relates to confidential HIV-related information, and Civil Rights Law 79-1, as it relates to confidential predisposition genetic testing information), as well as breach notification obligations under General Business Law § 899-aa..

- *Breach Notification and Payment of Costs Related to a Breach*

Provisions should be included specifying the procedure for determining a data breach. A determination of whether a breach has occurred should be within the control of the System and should be so specified in the IRB Authorization Agreements. Provisions should also be included regarding payment for the costs of such breach.

26) Only the BRANY Agreement includes a BAA and only the BRANY and Western Agreements have provisions addressing privacy and security of confidential subject information. Although the Western Agreement discusses confidentiality, it does not discuss Public Health Law Article 27-F confidentiality and training requirements, or mention Civil Rights Law 79-1, or address General Business Law 399-dd and 899-aa private information confidentiality and data breach requirements, costs, and responsibilities.

Contract Deficiency 8: Compliance with Applicable New York State Law

27) The System is responsible for ensuring that services provided in the Authorization Agreements comply with all pertinent provisions of NY State law. This requires that contracts, such as IRB Authorization Agreements, meet certain regulatory requirements. Only the BRANY agreement included reference to the following regulations:

- *10 NYCRR 400.4 Contracts*

According to the minimum standards and general requirements for medical facilities under the DOH regulations, contracts to perform any services for a medical facility should include each party's "responsibilities, functions, objectives, financial arrangements, and charges." Hospital service contracts should also include the following required language: "Notwithstanding any other provision in this contract, the facility remains responsible for ensuring that any service provided pursuant to this contract complies with all pertinent provisions of Federal, State and local statutes, rules and regulations."¹²

¹² 10 NYCRR § 400.4 (a)(4)

- *10 NYCRR 405.2(h) Hospital Service Contracts*¹³

Hospitals are responsible for services within the hospital whether they are furnished internally or by outside entities under contracts. The services performed under a contract should be provided in a “safe and effective manner.”

Contract Deficiency 9: Medicare Conditions of Participation - 42 CFR 482.12(e) Contracted Services

28) Medicare conditions of participation require that hospitals must ensure that a contractor of services furnishes services that “permit the hospital to comply with all applicable conditions of participation,” and they must ensure that “the services performed are provided in a safe and effective manner.”¹⁴

Only the BRANY Agreement addresses the New York requirements, which are similar to and stem from the Medicare contractor requirements.

Contract Deficiency 10: Conflicts of Interest

29) The IRB shall report any conflicts of interest it learns during the course of its oversight activities to the Conflicts of Interest Committee at the System. Only the BRANY and Maimonides agreements have conflict of interest provisions.

Contract Deficiency 11: Standard Legal Terms and Conditions (Legal Boilerplate)

30) IRB Authorization Agreements should contain standard legal terms and conditions, including without limitation, specific sections regarding Insurance, Indemnification, Term and Termination, Choice of Law, Venue, Confidentiality, and Miscellaneous provisions including, without limitation, Force Majeure and Survival. Also, with regard to the venue provisions, all Agreement should comply with the venue provisions in the NYC Health + Hospitals enabling statute. Only the BRANY and Western Agreements have these standard legal terms and conditions.

¹³ 10 NYCRR § 405.2 and 10 NYCRR 400.4 are implementing regulations authorized in PHL § 2803-a. PHL 2803-a, which authorizes hospitals to enter into contracts for the joint purchases of goods, supplies and services.

¹⁴ 42 CFR § 482.12(e).

Summary of OCC Recommendations

Recommendation 1

31) The IRB Authorization Agreements should be renegotiated as they expire or are amended to include the key contract terms described in detail above. Several of the IRB Authorization Agreements were signed almost ten (10) years ago. Accordingly, the Agreements should be updated to ensure compliance with current legal and regulatory requirements. The BRANY IRB Authorization Agreement, which had expired but was recently extended, can serve as a template for all IRB Authorization Agreements used within the System.

Management Response: ORA agrees with this recommendation and is working with OLA to revise or amend the IRB Authorization Agreements as appropriate.

Recommendation 2

32) The services provided by the IRBs should be reviewed to determine if non-standard research oversight services are being provided requiring a BAA.

Management Response: ORA agrees with this recommendation and is working with OLA to determine if any BAA are required. At this point there does not appear to be a need for a BAA other than with BRANY.

Recommendation 3

33) All IRB Authorization Agreements should reviewed by OLA as to legal form as required by OP 180-9. The OCC will continue to work with OLA and ORA to ensure that all new IRB Authorization Agreements follow the BRANY IRB Authorization Agreement as closely as possible and assist in drafting required language.

Management Response: ORA agrees with this recommendation and is working closely with OLA on IRB Authorization Agreements.

Additional Management Response

34) In addition to the management responses provided above, management commented that:

- In its oversight of all human subjects research, ORA (including its investigators, research staff, residents involved with the conduct of human research, the IRBs, System official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines

for the Protection of Human Subjects of Research,” also known as “The Belmont Report.”

- NYC Health + Hospitals Research complies with all Federal regulations regarding objectivity in research and the Board-approved 2015 Human Subject Research Protections Program Policies and Procedures. The System engages only IRBs that are guided by the ethical principles established by the Belmont Report.

II. Summary of Compliance Reports for the Second Quarter of Calendar Year 2017

1) For the second quarter CY2017 (April 1 to June 30, 2017) there were 80 compliance-based reports (“Reports”) of which 27 (33.8%) were classified as a Priority “B”; and 53 (66.2%) were classified as a Priority “C”.¹⁵ The majority of reports, 41 (51.2%) were received through the Confidential Compliance Helpline. The next largest source of Reports received was e-mail, which accounted for 12 (15%) of the reports. A complete analysis is set forth below.

Report Analysis

2) For purposes here, the term “Reports” means compliance-based inquiries and compliance-based complaints. The breakdown of 2nd quarter reports by subject, source and allegation are as follows:

A. By Subject



¹⁵ There are three (3) different report categories: (i) Priority “A” reports - matters that require immediate review and/or action due to an allegation of immediate threat to a person, property or environment; (ii) Priority “B” reports – matters of a time-sensitive nature that may require prompt review and/or action; and (iii) Priority “C” reports – matters that do not require immediate action.

CHART DATA

	Frequency (Percentage)
Diversity, Equal Opportunity and Respect in the Workplace	9.0 (11.2 %)
Employee Relations	19.0 (23.8 %)
Environmental, Health and Safety	9.0 (11.2 %)
Financial Concerns	3.0 (3.8 %)
Misuse or Misappropriation of Assets or Information	14.0 (17.5 %)
Other	10.0 (12.5 %)
Policy and Process Integrity	16.0 (20 %)
Totals	80.0 (100%)

B. By Source

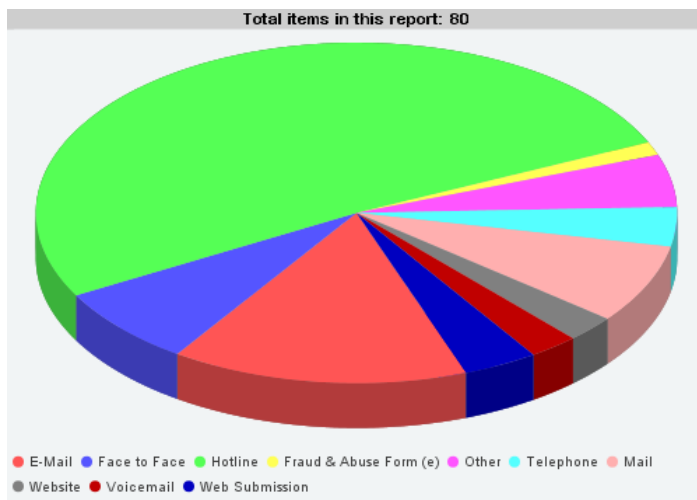


CHART DATA

	Frequency (Percentage)
E-Mail	12.0 (15 %)
Face to Face	6.0 (7.5 %)
Fraud & Abuse Form (e)	1.0 (1.2 %)
Hotline	41.0 (51.2 %)
Mail	6.0 (7.5 %)
Other	4.0 (5 %)
Telephone	3.0 (3.8 %)
Voicemail	2.0 (2.5 %)
Web Submission	3.0 (3.8 %)

Website	2.0 (2.5 %)
Totals	80.0 (100%)

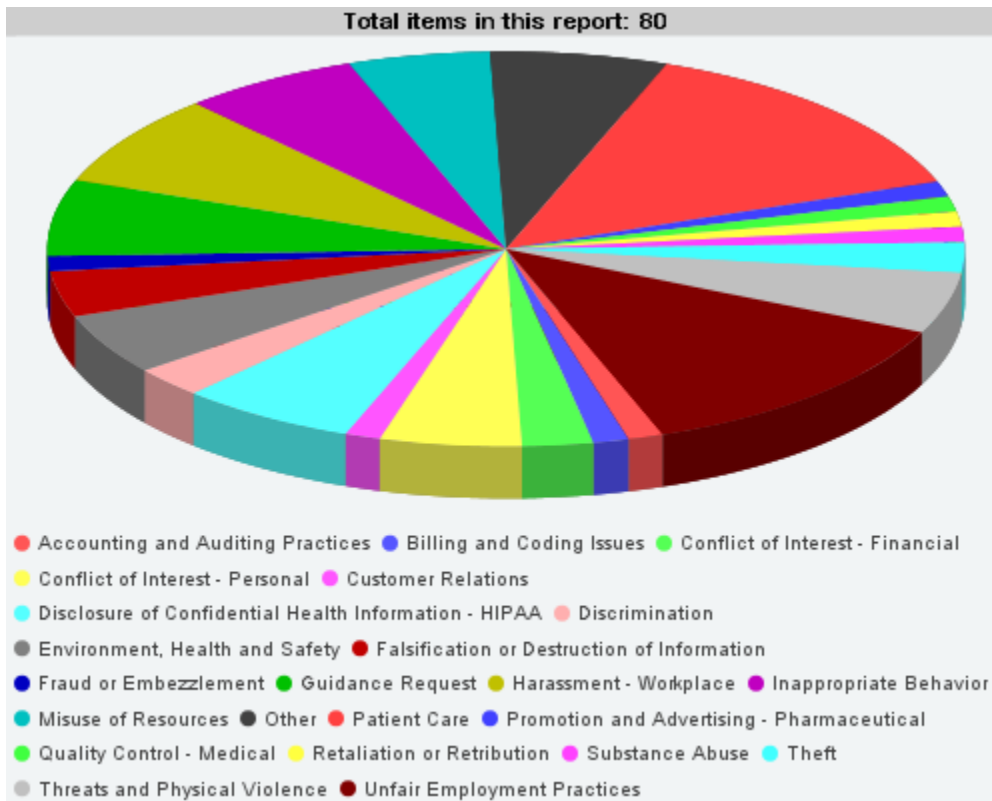


CHART DATA

	Frequency (Percentage)
Accounting and Auditing Practices	1.0 (1.2 %)
Billing and Coding Issues	1.0 (1.2 %)
Conflict of Interest - Financial	2.0 (2.5 %)
Conflict of Interest - Personal	4.0 (5 %)
Customer Relations	1.0 (1.2 %)
Disclosure of Confidential Health Information - HIPAA	5.0 (6.2 %)
Discrimination	2.0 (2.5 %)
Environment, Health and Safety	4.0 (5 %)
Falsification or Destruction of Information	3.0 (3.8 %)
Fraud or Embezzlement	1.0 (1.2 %)

Guidance Request	5.0 (6.2 %)
Harassment - Workplace	6.0 (7.5 %)
Inappropriate Behavior	5.0 (6.2 %)
Misuse of Resources	4.0 (5 %)
Other	5.0 (6.2 %)
Patient Care	11.0 (13.8 %)
Promotion and Advertising - Pharmaceutical	1.0 (1.2 %)
Quality Control - Medical	1.0 (1.2 %)
Retaliation or Retribution	1.0 (1.2 %)
Substance Abuse	1.0 (1.2 %)
Theft	2.0 (2.5 %)
Threats and Physical Violence	4.0 (5 %)
Unfair Employment Practices	10.0 (12.5 %)
Totals	80.0 (100%)

C. By Priority

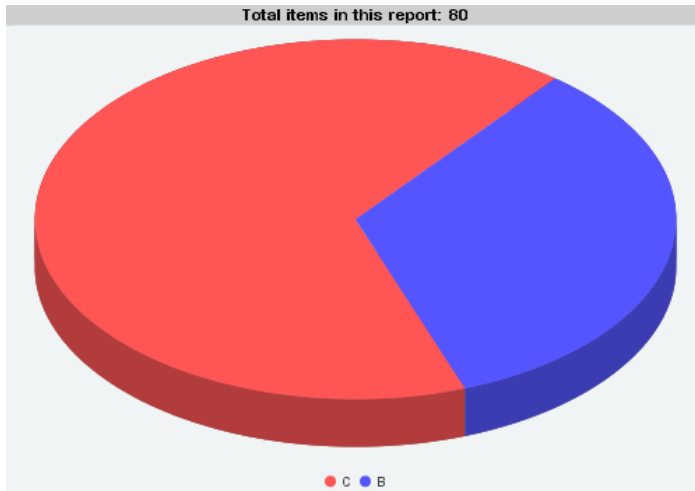


CHART DATA

	Frequency (Percentage)
B	27.0 (33.8 %)
C	53.0 (66.2 %)
Totals	80.0 (100%)

III. Monitoring of Excluded Providers

Overview of Regulatory Requirements

1) Federal regulations prohibit the allocation of Federal health care program (*e.g.*, Medicaid, Medicare) payments “for any item or service furnished . . . by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.”¹⁶ Likewise, New York State (the “State”) has promulgated billing prohibitions related to services furnished by an excluded provider. Lastly, to maintain an active enrollment status in the Medicare program, NYC Health + Hospitals must certify that it does not employ or contract with individuals or entities that are “excluded from participation in any Federal health care programs for the provision of items and services covered under the programs.”¹⁷

Responsibilities of the System for Sanction List Screening

2) To adhere to these regulations, and consistent with the recommendations of the NYS Office of the Medicaid Inspector General (“OMIG”)¹⁸ and the United States Department of Health and Human Services Office of the Inspector General (“OIG”), each month the Office of Corporate Compliance (“OCC”) reviews the exclusion status of the NYC Health + Hospitals workforce (*e.g.*, employees, board members, affiliates, personnel, volunteers, and medical staff members), vendors, and DSRIP partners.

Office of Foreign Asset Control (“OFAC”) Screening

3) To ensure that NYC Health + Hospitals does not conduct business with individuals or entities that are a threat to the security, economy, or foreign policy of the United States, the OCC also screens all NYC Health + Hospital Workforce members, vendors and DSRIP partners against the data bases of the U.S. Department of Treasury Office of Foreign Asset Control (“OFAC”).¹⁹

¹⁶ Scope and Effect of Exclusion 42 CFR § 1001.1901 (b); *see also* 42 CFR § 1002 (the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity).

¹⁷ *See* 42 CFR § 424.516 (a) (3); *see also* 42 CFR § 424.535(a) (2) (regarding CMS’ option to revoke enrollment and billing privileges due to exclusion from Medicare, Medicaid or any federal program). *See also* 42 USC 1320c-5 (Regarding obligations of health care practitioners and providers and the Secretary of Health and Human Services ‘right to exclude a person or entity for failing to meet the obligations.)

¹⁸ DOH Medicaid Update April 2010, Vol.26, No. 6 and the NY OMIG webinar #22 OMIG Exclusion and Reinstatement Process, <https://omig.ny.gov/resources/webinars/811-omig-webinar-22> [Slide 20 (Sept 2014), accessed Feb. 2, 2017.]

¹⁹ *See* Frequently Asked Questions: **Who must comply with OFAC regulations?** United States Treasury website, https://www.treasury.gov/resource-center/faqs/Sanctions/Pages/faq_general.aspx [accessed Feb. 1, 2017.]

Exclusion and Sanction Screening Report

4) Since the OCC last reported excluded provider activities at the June 13, 2017 Audit Committee, one excluded provider and one suspended provider were identified.

5) On July 6, 2017, OCC was informed that a physician on the System's list of community physicians, who referred home care patients to NYC Health + Hospitals' Certified Home Care Agency ("CHHA"), is excluded by OMIG, effective June 5, 2017. This community physician has not referred a home care patient to NYC Health + Hospitals' CHHA since 2016. Therefore, his recent OMIG exclusion did not create any potential overpayment issue to address. NYC Health + Hospital's At Home staff has been informed that any future patients this physician refers must be assigned to another physician for continued services at NYC Health + Hospitals.

6) On June 22, 2017, OCC was informed that the license of a health care professional working at Gotham / East New York Diagnostic and Treatment Center was suspended for two (2) months, effective May 24, 2017. On May 24, 2017, the counselor saw three (3) patients. The OCC has received written confirmation from Patient Accounts that billing has been suspended for one (1) unbilled visit. As for each of two (2) remaining patient visits made by the counselor on May 24, 2017, a corresponding refund has been submitted. The Office of Labor Relations and the Office of Legal Affairs are evaluating the potential scope of disciplinary action the health professional may face in this matter.

Death Master and NPPES Screening to Prevent Identity Theft

7) Center for Medicare and Medicaid regulations²⁰ and the contractual provisions found managed care organization ("MCO")²¹ provider agreements both require screening of NYC Health + Hospitals workforce members and certain business partners (collectively "Covered Persons") to ensure that none of these Covered Persons are using the social security number ("SSN") or National Practitioner Identification Numbers ("NPI") of a deceased person in an effort to hide their true identity. This screening may be accomplished by vetting the SSNs and

²⁰See CMS's Toolkit to Address Frequent Findings 42 CFR § 455.436 Federal Database Checks, <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/Downloads/fftoolkit-federal-database-checks.pdf> (accessed June 1, 2017), see also generally, 42 CFR § 455.436;

²¹"Provider ... agrees to monitor its employees and staff against the List of Excluded Individuals and Entities (LEIE), the Social Security Administration Death Master List, and the National Plan Provider Enumeration System (NPPES)".

New York State Department of Health Standard Clauses for Managed Care Provider/IPA Contracts, Appendix Revised April 1, 2017, at 4, available at: https://www.health.ny.gov/health_care/managed_care/hmoipa/docs/standard_clauses_revisions.pdf, (accessed June 1, 2017).

NPIs of Covered Persons through the Social Security Administration Death Master File (“DMF”) and the National Plan and Provider Enumeration System (“NPPES”), respectively.

8) The OCC currently screens the DMF and NPPES files as part of its sanction screening process. There are no providers that have been identified on the DMF since the last time the Audit Committee convened in June 2017.

IV. Status Update - DSRIP Compliance Attestation of OneCity Health Partners

Background

1) As previously reported to the Audit Committee in April and June 2017, as a Performing Provider System (“PPS”) lead in the New York State Department of Health Delivery System Reform Incentive Payment (“DSRIP”) Program, NYC Health + Hospitals/OneCity Health (“OneCity Health”) is responsible for taking “reasonable steps to ensure that [M]edicaid funds distributed as part of the DSRIP program are not connected with fraud, waste, and abuse. It is reasonable for a PPS Lead to consider its network performing providers’ program integrity systems when dedicating resources and developing the PPS Lead’s systems.”²² To satisfy its compliance obligations as the PPS Lead and to fulfill the requirements of the Office of Medicaid Inspector General (“OMIG”) DSRIP compliance guidance, OneCity Health developed a compliance Attestation form, which was designed to assess the compliance program integrity of its Partners.

The Attestation Form, Process and Results

2) On February 2, 2017, the Office of Corporate Compliance (“OCC”) distributed a Memorandum and a Compliance Attestation to be completed by all OneCity Health Partners.

3) In the Attestation, OneCity Health Partners were asked to provide the following information to the OCC:

- The status of their completion of DSRIP compliance training (a training PowerPoint had previously been previously provided to the Partners);
- An acknowledgement that their workforce members have adopted the *NYC Health + Hospitals Principles of Professional Conduct (“POPC”)* or their own organization’s code of conduct that includes the POPC’s core objectives or substantially similar compliance goals;

²² Office of the Medicaid Inspector General Delivery System Reform Incentive Payment (“DSRIP”) Program DSRIP Compliance Guidance 2015-01 –revised – Special Considerations for Performing Provider System (“PPS”) Leads’ Compliance Program available at:

https://www.omig.ny.gov/images/stories/compliance_alerts/20150901_DSRIP_CompGuidance_2015-01_Rev.pdf

- Proof of New York State Office of Medicaid Inspector General (“OMIG”) compliance program-related certifications by Partners that are required by law and/or OMIG policy to submit such certifications; and
- Confirmation that they were routinely screening their workforce members for exclusions from Federal healthcare programs and government contracting.

4) The two OMIG compliance certifications referenced in paragraph 3 of this section are as follows:

- New York Social Services Law § 363-d Certification; and
- The Deficit Reduction Act of 2005 (“DRA”) Certification.

5) The answers provided by the Partners in the Attestation will be utilized by the OCC to:

- Assess the compliance program integrity of its Partners; and
- Satisfy OneCity Health’s DSRIP Program compliance oversight obligations as they relate to the allocation of DSRIP funds.

Status of Compliance Attestations

Previous Partner Count

6) As noted in the April Audit Committee report, Attestations were sent to 228 Partners. The methodology utilized to count partners has since been revisited and revised.

Current OneCity Health Partner Count

7) As explained in the June 2107 Audit Committee report, for purposes of DSRIP contract execution, NYC Health + Hospitals OneCity Health counts partners at the system level. Moving forward, Attestations will be counted utilizing the same methodology. For example, Community Healthcare Network would count as 1 partner (system), comprising of > 5 sites. Thus, the number previously used by the OCC and reported to Audit Committee - - n = 228 - - was pulled from a OneCity Health newsletter distribution list, which contained duplications, or multiple contacts within same partner system. The de-duplicated number is n=203.

8) The OneCity Health team and the OCC have decided that the target group (or “denominator”) for attestations would be limited to those who would execute a Schedule B for time period of April 2017 to December 2017. The Schedule B is a contract that outlines performance requirements to earn DSRIP funding (“funds flow”).

- Of 203 who could potentially sign a Schedule B, 193 have completed the same;
- At the June Audit Committee, the OCC reported that of the 193 who have actually signed the Schedule B, 157 completed the attestation; and
- As of August 31, 2017, of the 193 who have actually signed the Schedule B, all 193 (100%) have completed the compliance Attestation.

9) The OCC has initiated an assessment of the responses provided by the Partners and will perform a risk analysis to determine what further compliance oversight activities are required. Preliminary assessment has yielded the following data:

- Of the 193 returned attestations, 126 have certified prior to or on December 31, 2016 with OMIG that they have an effective compliance program that meets the requirements of New York Social Services Law § 363-d 18 NYCRR Part 521;
- Of the 193 returned attestations, 93 have certified prior to or on December 31, 2016 with OMIG that they have met the DRA requirements.
- Of the 193 returned attestations, 11 have certified that they do not screen their workforce members and contractors against Federal and State exclusion lists on a monthly basis. Additionally, some Partners omitted answering this question on their Attestation; as such, the OCC will be following up with these Partners.

10) In the upcoming days, each Partner will receive notice from the OCC reminding them of their exclusion screening obligations under regulatory guidance and the DSRIP Master Services Agreement between the Partner, NYC Health + Hospitals, and OneCity Health Services.