AUDIT COMMITTEE
MEETING AGENDA

April 04, 2017
1:00 P.M.

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

CALL TO ORDER — Ms. Emily A. Youssouf

- Adoption of Minutes February 10, 2017 — Ms. Emily A. Youssouf

INFORMATION ITEMS

- Audits Update — Mr. Chris A. Telano
- Compliance Update — Mr. Wayne McNulty

EXECUTIVE SESSION

OLD BUSINESS

NEW BUSINESS

ADJOURNMENT

MINUTES

AUDIT COMMITTEE

MEETING DATE: February 10, 2017
TIME: 1:00 PM

COMMITTEE MEMBERS
Emily Youssouf, Chair
Stanley Brezenoff
Josephine Bolus, RN
Mark Page

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
Wayne McNulty, Corporate Compliance Officer/Senior Assistant Vice President
Machelle Allen, Interim Chief Medical Officer, Medical & Professional Affairs
Imah Jones, Senior Director, Research Administration
Blanche Greenfield, Chief FMLA Counsel
Christopher A. Telano, Chief Internal Auditor/AVP, Office of Internal Audits
Devon Wilson, Senior Director, Office of Internal Audits
Chalice Piña, Director, Office of Internal Audits
Delores, Rahman, Director, Office of Internal Audits
Carlotta Duran, Assistant Director, Office of Internal Audits
Frank Zanghi, Audit Manager, Office of Internal Audits
Armel Sejour, Senior Auditor, Office of Internal Audits
Melissa Bernaudo, Senior Auditor, Office of Internal Audits
Gillian Smith, Senior Auditor, Office of Internal Audits
Jean Saint-Preux, Staff Auditor, Office of Internal Audits
Miriam Yeger, Staff Auditor, Office of Internal Audits
Sandy Bhigroog, Staff Auditor, Office of Internal Audits
Jessica Fortes, Staff Auditor, Office of Internal Audits
Peter Papadopoulos, Staff Auditor, Office of Internal Audits
Conny Lizarazo, Executive Secretary, Office of Internal Audits
Ron Townes, Associate Director, NYC H + H/Kings County
Martin Novzen, Chief Financial Officer, NYC H + H/Lincoln
Mutiu Agbosasa, Assistant Director, NYC H + H/Metropolitan
Jose Santiago, Controller, MetroPlus
Lilly Pham, Senior Assistant Controller, MetroPlus
Rosario Ceron, Director, MetroPlus
Steven Angelo, Assistant Director, MetroPlus
David Nunziato, Chief Financial Officer, NYC H + H/Woodhull
Joseph D'Agostino, Director of Pharmacy, NYC H + H/Jacobi
Manfredo Pompa, Assistant Director of Pharmac, NYC H + H/Jacobi
Shamelle Watkins, Senior Associate Director, NYC H + H/Bellevue
Corliss Cobham, Assistant Associate Director, NYC H + H/Bellevue

OTHER ATTENDEES
PAGNY: Anthony Mirdita, Chief Financial Officer

FEBRUARY 10, 2017
AUDIT COMMITTEE MEETING
MINUTES

A meeting of the Audit Committee was held on Friday, February 10, 2017. The meeting was called to order at 1:02 P.M. by Mrs. Bolus, Committee Member. Mrs. Bolus stated that because we do not have a quorum, we are going to by-pass the minutes and go straight to the information items.

Mr. Telano saluted everyone and said that we will start with an on-going external audit, a summary of the audit being done by the New York City Comptroller's Office. They have been gathering information since they started in September, and they are scheduled to begin their field work in mid-March.

Moving on to the completed internal audits. The first one was a review of FMLA and other leaves of absences done at Bellevue. Mr. Telano asked for the appropriate representatives to come to the table.

Mr. Russo added that for the record, introduce yourself. They introduced themselves as follows: Kim Mendez, Chief Nursing Officer; Dr. Rosa Colon-Kolacko, Chief People Officer; Shamelle Watkins, Senior Associate Director; Corliss Cobham, Associated Director, Human Resources; Blanche Greenfield, Chief Employment Counsel; Mary Fritz, Senior Director of Leave Administration.

Mr. Telano continued and stated that during our review there were 357 nurses on various types of leave. Initially this audit was focused on family and medical leave, but it was extended to include continuous child care leave and continuous medical leave. We will go through all the findings first, and then you can provide your responses. The first finding, A, overall the Human Resources Benefit Department needs to improve their record keeping and timely communication within various aspects of the FMLA process, and there's some instances in which we found, the first bullet point indicates, that the recertification forms were being submitted between 162 to 182 days although their facility policy requested that those forms be submitted within 90 days.

During our review of 32 employees, we also found 12 instances in which Benefits notified Nursing of the approval an average of 23 days after receiving the medical certification. We found six employees that provided the Benefits Department with their medical certification in 16 to 24 days although it's required within 15 days. This indicates that Benefits did not follow up with the employees timely.

We also found ten instances in which the notice of designation, which is an approval for the FMLA requests, were not returned to the employees by the Benefits Department within the required working days. We found these forms were issued 6 to 23 days after receipt by Benefits. We also found seven instances in which an employee was denied an FMLA leave and was granted a different type of leave. However, there was no documentation in their files to indicate that the employees had been notified of the FMLA denial. We also noted that of 89 employees, 22 of the medical certification forms were not dated to indicate the day that they were received by the Benefits Department. We recommended that they start stamping these forms, and they implemented that during the course of the audit.

Moving on to finding B in the briefing, we noted that while Benefits stated it is part of the process to authenticate the physician signatures, we found no evidence of this during our audit. Many forms included the stamp of the doctors or the name of the doctor on the heading of the fax, but in some instances that was not indicated. It was only hand written either by the employee or the Benefits Department; and in 4 instances we found that the signature of the physician was illegible.

The Benefits Department could not provide a complete list of nursing personnel on FMLA or other types of leave due to a short coming within the PeopleSoft system. We believe this led to one employee taking FMLA time in excess of the allowable amount and also one employee indicating 23 hours and the Timekeeping System showing only 11.3 hours. It should be noted that PeopleSoft was updated to generate a report with a special code to indicate employees on FMLA.

Mr. Telano asked the representatives to respond to issues in the order I presented them.

Ms. Watkins said that in regard to finding A, there were some staffing shortages at Bellevue during the auditing period, but generally we agree that there have been some flaws in the manner which LOAs were administered at Bellevue and probably throughout the System. It is for this reason we decided even before the audit at Bellevue to standardize leaves of absences across the System and centralize how they are administered to prevent these inaccurate outcomes.

We have developed a work group, which began meeting in October of this past year, to develop a standard procedure. The work group consisted of Facilities Labor, Legal and HRSS. The outcome of their efforts resulted in a draft of leave of absence operating procedure, which addressed all the concerns of this audit and which also includes certain other innovations such as electronic rather than paper files. The operating procedure is in legal review now and will be submitted promptly for management review, approval and implementation. A similar OP will be drafted for our Workers' Compensation claims and implemented as well.

We began a centralized pilot in January of leaves with some other sister facilities, Coler, Carter and Gouverneur, which is providing lessons about proceeding with centralized leaves of absence across the entire health system.

Dr. Colon-Kolacko reported that we are also in the process of centralizing this process for the whole system, and we're in the process of finding a location. We have started drafting standardized processes, and we're expecting to be able to centralize it by even this fiscal year, June 30th, so we are on target to do that.

Ms. Greenfield added that I don't know that we necessarily had some legal issues. There were some concerns about different implementation in different systems. Now that we've had the opportunity to look at what's going on facility-wide, we want to make sure that everybody is on the same page. A law can be read in different ways, and we all want to read it one way consistently in the way that the courts have supported it, and that's what the chart Ms. Fritz and Dr. Colon-Kolacko have been working on now.

Mr. Page asked how is the information on this subject going to be available to your employees who are affected by it?

Ms. Fritz responded that we are going to use a lot of different verification methods. Flyers, we're going to use screen savers. We're going to be putting forms and processes, how-to-steps on our website. We are going to go out to each of the facilities and talk to the various departments within the facilities, and employees. We are going to be passing things out to them so that everybody knows what we are doing and when we are going to do it.

Mr. Page asked if there will be somebody so that if I'm an employee and coming up on an FMLA question, there will be somebody who will tell me and direct me where I can actually read an understandable explanation of what I'm coming up against.

Ms. Fritz answered that the Human Resources offices will still be located in each of the facilities, and they can also be a resource for information, but we hope to communicate it so well that employees know to go directly to our website or to use our phone number. They can also call us by phone, and we will direct them. We have Employee Self Service (ESS) stations. We have computer stations, kiosks, in all of the facilities where employees can go and print out the forms, and soon the whole process will be electronic, so they will be able to in put their information directly into the system.

Mr. Page stated that you can put out the information, but until I am faced with the issue myself, it flashes by, and then it's just a question of how to hook into it easily and get it again.

Dr. Colon-Kolacko added that I think in addition to our employee portal, we have a liaison at every facility so that if an employee has questions, they can call our help desk or contact a liaison locally at HR.

Mr. Russo reported that we happen to have within my office an expert on FMLA who previously got her experience litigating on behalf of the City those very issues in Ms. Blanche Greenfield.

Ms. Greenfield said that FMLA is very well known among our employees, and it's a benefit, a statutory benefit that is used and I must say anecdotally the people at the facilities are very, very helpful with our employees ensuring that they get the paperwork and complete it so that they can be approved when it's needed.

Dr. Colon-Kolacko stated that the process will also improve HR being able to track it better. Also to follow up. Sometimes it's important. The best practice is to follow up when an employee is out for a longer period of time so we can identify any help and how can we make sure they can come back, and also if they need any help, we can proactively address that.

Mrs. Bolus asked if you are making major changes in this new policy you are putting out compared to the old.

Dr. Colon-Kolacko answered no, I think the major changes is the visibility, the tracking, the better communication and also be able to identify the different categories of when people are out so we can also prevent costs and also address the needs of the employees more practically.

Ms. Greenfield added that for the employee there will be no change, it's the same guidelines. For us, in terms of being better able to see our population, the ability to bring them back sooner if they have a medical restriction, that's what will change so we can better serve our people and bring them back who may not be able to perform all of their duties but they can perform their essential duties if they need a reasonable accommodation. We don't want them sitting home. We want to bring them back to work, and this will allow us to do that.

Mr. Telano asked is there any other questions?

Mr. Page stated that I would like to go back in the agenda. I apologize that I was not here, so I understand you did not have a quorum. Could I go back to the adoption of the minutes, and could I have a motion to approve the minutes of December 8, 2016? A motion was made and seconded with all in favor.

Mr. Telano stated that the next item is an audit of research protocols at Lincoln and the Corporate Research Administrative Department. He asked for the representatives to come to the table. Mr. Telano informed the Committee that after his presentation the reporting will segue on to Mr. McNulty's compliance presentation related to research as it would be redundant for those individuals to come back to the table later on in the meeting.

Mr. Russo asked the representatives to identify themselves for the court reporter. They did as follows: Dr. Machelle Allen, Interim Chief Medical Officer; Martin Novzen, Deputy CFO, Lincoln; Dr. Balavenkatesh Kanna, Research Director, Lincoln; Dr. Imah Jones, Senior Director, Central Office.

Mr. Telano reported that we conducted an audit of the research protocols previously in the beginning of 2015 at the Queens facility. The report was presented at the Audit Committee in June 2015, and one of the issues we noted was that there was no centralized over sight or monitoring of the corporate-wide research protocols by the Corporate Research Administration Department. At that meeting, the Senior Director of that Department and the Corporate Chief Medical Officer at that time, they both agreed to initiate action to centralize the oversight and the monitoring.

Now we have conducted this audit in 2016, and we found that there was no or minimal action taken to centralize the function, and some of the observations we made to support our conclusion was that certain documents were not uploaded to the database that houses all research documents, the STAR application. We also found that Research staff who were not approved to handle research studies at Lincoln had no training documents on file, which is also the responsibility of the Corporate Administration Department. We also noted that there was no consistency with the recording of research activity, consent forms within the QuadraMed medical records system. They were utilizing different modules within the system to put the information, so you would have to spend time looking for it, but there is a research option within the system where everything should be going.

We also noted that Corporate Research Administration is not monitoring payments due to New York City Health + Hospitals. We found one study in which bi-monthly payments were never submitted, and there were six bi-monthly payments over the course of the audit. The monthly payments should have been $3,900, and another study in which invoices were submitted 218 to 601 days late.

The other issue has to with the setup of the Clinical and Community Research function within New York City H + H/Lincoln. The research staff for one study was not approved by the Institutional Review Board (IRB), resulting in four patients being improperly consented and hence removed from a cancer screening study. Principal investigators did not report eight deviations and/or violations to the Corporate Research Administration as required per the Operating Procedures, and some of the deviations were improper consent forms, missing patient files, research specimens not being delivered to the lab for analysis and improper specimen analyses being sent to the lab.

We also noted that five Serious Adverse Events that occurred in two studies were not reported to BRANY, which is the Biomedical Research Alliance of New York, IRB as required by Operating Procedures. Four of the five patients in this study experienced low blood sugar while one experienced stroke like symptoms. They should have been reported.

Mr. Telano asked for a response to the findings just summarized.

Dr. Jones responded that we agree initially with the findings as just expressed. However, during our last meeting here, we were clear that we were going to monitor the continual renewal of all activities here at H + H. However, the focus was continuing this process within the System with STAR. Our promise was to modify that system to start that process. However, we are doing it offline to be able to have the information that was requested and ordered by the Audit Committee and that is what we are doing and it has been working. However, we have been working to see if we can modify our STAR system to be able to include that information. We are going to fully implement it but we are doing it offline, so we'll be able to answer the question the cost and benefit analysis of doing it and then the transitional figure to be able to fully implement it within the STAR system.

Mr. Page asked what exactly are you doing offline? To which Dr. Jones answered that when you want to conduct a study at H + H, you are required to have an approval, so each study has an initial approval good for only 1 year. After that one year, you are required to renew that study to continue. However, we don't have that process incorporated in the system. The only process that was required and incorporated in our Operating Procedure is the initial approvals. During that audit they said it would be nice if you also the renewal process be implemented or be included also in our system. What I'm saying is that the system as designed does not contain that process, and that's what we are doing to include in the system.

Mrs. Bolus asked that if the first approval was given for the first year, and the second year there was no approval for that group, can you still utilize that information in the same research project if it's not been approved.

Dr. Allen responded that I think what we are talking about is documentation and tracking of continuation and re-approval. Currently it does not exist in the STAR system, has not existed, so we have to buy software to modify the STAR system. You are absolutely right, you cannot continue without approval, but you have to document that you got approval. You have to be able to track that. While we are moving forward with purchasing the appropriate software to supplement the STAR system, it is being done offline. So there is at least tracking, but you can't audit it.

Mr. Brezenoff asked how big this study is. To which Dr. Jones responded that as of this afternoon, there are 1100 active studies.

Mr. Brezenoff then commented that it is a little hard to track manually, but you are trying.

Dr. Jones stated that all of them are not due at the same time. For example, the system that we have now will be able to show within the next 60 days how many out of that 1100 about 12 of them. So we have a tracking system that helps us do that, but what this is requesting is to automatically do that, and what Dr. Allen is saying is we are in the process of getting the software to enable automatic tracking.

Mr. Brezenoff stated that there are such things as calendar indexes, right, where you put a sheet in for the relevant month and then check that month prior to its beginning and see what's in it. There are things like that pre date computers.

Mrs. Bolus asked why it wasn't anticipated that you had to do it within one year.

Dr. Jones responded that it was anticipated. However, the IRB was doing that part already, so we thought it was redundant for H + H to do it since somebody else was doing it.

Mrs. Bolus asked how much was lost. How much data is not usable because it was not within the actual allotted time.

Dr. Allen responded that since STAR was implemented, which was 2015, none of that has been tracked.

Mrs. Bolus once again asked how much was lost. Dr. Allen answered that since STAR was implemented, over a year.

Mrs. Bolus stated so about a year's data is not being able to be used.

Dr. Allen stated that in terms of continuation of studies, not approval of studies.

Mr. Russo added that it was the tracking of the study, so the studies continue.

Mrs. Bolus stated that the studies may continue, but you have an okay for one year, and you don't have an okay for the second year. To my mind, and I have not done much research, it's been a long time, if you don't have the okay for that second year that data is not viable.

Dr. Allen responded no, it's not that we didn't we have the okay. We had the approval. It was tracked manually, but it was not placed into the electronic system. Everything that is current has been approved.

Mr. Telano stated that it should be noted that during the course of our audit none of the manual files were provided to us for review.

Mr. Page asked if Internal Audits asked for them. To which Mr. Telano responded we did.

Mrs. Bolus asked where the files were.

Dr. Jones answered that the information was provided. The requested information in the beginning was not there. We are providing information – we are tracking the information, it is readily available.

Mr. Russo added that BRANY, the IRB, would have that information, but you did not have it in your file, but they were approved, and you can get them from BRANY, but you did not have them at the time to provide.

Dr. Jones answered yes.

Mrs. Bolus asked how we are going to correct that if this happens again. Will it happen again?

Dr. Jones responded that it will not happen again because as I pointed out it was not part of our Operating Procedure. Now it has been incorporated, and we are tracking it. Next time it is going to be automatic. Although the Interim President tells me to go back and start tracking it, we are going to do it. It is not going to be an issue moving forward.

Dr. Allen added that it is not available in our system. It is available in the IRB system. It was producible on demand. It exists, not in our system, the STAR system, but every research that we do is IRB approved and reapproved according to regulation standards. From that perspective, there is no harm. The harm is when we are audited and asked to produce. At this particular time because of the electronic system we have in place, it could not be produced in a timely fashion, so the people who were audited had to go back, find the back-up documents to present them.

Mrs. Bolus asked if that's been done?

Dr. Allen responded yes.

Mr. Telano added that not to us.

Mr. Russo stated that you should make sure that he gets proof that all the studies were approved.

Mr. Telano stated that we will look at that at our follow up audit to make sure everything is there.

Dr. Kanna reported on the ID system that was brought up by Mr. Telano. The ID system already has an existing note, which is on the outpatient side. We are currently trying to migrate it to the inpatient side. Some of the studies were inpatient studies, so we did not have a proper note. All the documentation is on other sites of the system and the doctors' notes. The auditors found that we need to use a dedicated research note as Mr. Telano was pointing out, so we are in the process of requesting that, and we are expecting that QuadraMed, the rollover that needs to take place before the note is to be migrated, and once that is, we will be able to allow the physicians to use that dedicated research in in patient studies.

Mr. Telano asked addressing the payments and the adverse conditions, events that occurred, who is going to address that, the deviations and the violations.

Dr. Jones restated that before the OP was instituted last year, there was not a clear delineation of responsibilities between Central Office and each facility that performed research. Therefore, we are also anticipating that the facilities are looking at us to say, unfortunately, there is this misunderstanding. That having cleared, we have fully submitted the invoice, and H + H will be reimbursed for the amount that they define in the findings by Mr. Telano.

Mr. Novzen added that going forward Lincoln and Central Office are planning to first, we are going to have monthly meetings within Lincoln itself at which time the financial aspect will be a permanent part of the a agenda. Going on to quarterly meetings between Central Office and Lincoln is going to take place, and again the financial aspect will also be a permanent part of the agenda. What that will show in real time is that the invoicing that has taken place was scheduled to take place, and I suspect that an aging of the payments of those open invoices to be also shown and illustrated at that time. We also wanted to establish a unique invoice number for each invoice because when the payment comes in on the check, there is no easy way - - it comes in to Central Office let me add. There is no easy way to discern what grant that is for, so we are going to establish a unique invoice numbering system, so that will be easily identifiable, and the application to the open invoice will be made.

Mr. Page commented that I guess I'm just demonstrating my dismal ignorance and difficulty understanding what you are actually doing. It would seem to me that the approval, the annual approval, is obviously a step which is required of you, but there seems to be a bunch of ancillary problems having to do with the administration of a particular research project pursuant to the approval. It just strikes me that the difficulty of access to the approval process that we have at least up to now been using, I gather doing it offline, is perhaps I mean more of a practical difficulty than you are saying, and I would imagine that it's at least some part of the cause of the flaws in the adhering to the administrative protocols on the given research projects. I am understanding from you, I think, that you are planning to transition to an automated approval system, but is that going to actually enable you to better connect the conditions dictated in the approved project to how the project is actually administered?

Dr. Jones stated that the answer is yes. Again, my view of what you are saying is what is happening here is before last year there was no consistent operating procedure that is standardized across the System. This is the first time that H + H has an operating procedure that covers all facilities, so in a way what you are seeing is a transition from almost nothing to a standardized format. So every person is transitioning from nothing almost to something. That is why you are seeing that influx. However, that is consistency from the approval process, but the billing process, which we are discussing, however, before then no person knows what they are supposed to be doing when this activity hit or happened.

Now there is a formal system dictated by the OP, which we are now complied to. Every person now knows the rule from the time to conduct research here until the time you close down the site. That is the formal process now. There was no formal process when the activity we are now discussing happened.

Mr. Page commented that I'm obviously concerned about the results of the audit, but I'm actually more concerned about the underlying practice or unevenness of the underlying practice that it seems to have brought up. We are moving to a consistent protocol, and I guess that is good if we manage to adhere to that one more successfully than we've adhered to our previous processes.

Mr. Russo added that I just want to clarify the record a little. We have had an operating procedure related to research that was approved by the Board for many years. We did not have a centralized function to research for over sight. That was recently in the past two years or so in a new operating procedure that was again approved by the Board, so it is not like we did not have anything in the past. More of the responsibilities in

the past were on the local level. Now we are more approaching it from a system-wide level, and in the course of this discussion here it was not so much that the approvals were not appropriately done.

We have had IRBs, and the IRBs are primarily responsible for insuring compliance with the research protocols, making sure they get reapproved, and the importance of the findings was that certain information did not get back to the IRB. That is significant but we have had all the approvals. It just was that centrally we did not have them at the time of the audit and also locally. The IRB had the approvals. We did not. It is important for me to say this because I don't want our record to reflect that in some way we were out of compliance with the federal rules regarding Human Subject Research.

Mr. McNulty stated that I'm going to continue on a review that we did at Human Subject Research at NYC Health + Hospitals. By way of background, and Mr. Russo had alluded to this, in late 2010 the Office of Legal Affairs, when I was a member and executive counsel in the office, the Office of Medical and Professional Affairs determined that the system's research policies and procedures required revision. Both of these offices moved in a multidisciplinary collaborative approach to develop and revise the research policies and procedures. At that time there was a research policy and procedure that was promulgated in 1991 and approved by the Board of Directors by full resolution of the Board.

Then we worked with the Office of Research Administration, the Office of Corporate Compliance, and the Office of Legal Affairs, to develop the new operating procedure 180-9, which governs Human Subject Research Protections throughout the System. That operating procedure was approved by the full Board of Directors by a resolution in November 2014 and executed by the System's President and CEO in April 2015.

The Office of Corporate Compliance in 2016 performed a review of an audit of whether or not we are complying with OP180-9 as now promulgated. We reviewed 30 studies from six acute care facilities and two Gotham Health facilities. The six acute care facilities were Bellevue, Elmhurst, Jacobi, Kings, and Queens. The two diagnostic treatment centers were Morrisania and Belvis. Out of those 30 studies, during the audit we learned that two did not require IRB approval because they were exempt from review. They did not meet the criteria, so we only looked at 28 studies. Out of the 28 studies, we noticed that there were four process and flow documentation findings that were identified and subsequently resolved.

First was at Kings, a study requiring continuing IRB approval documentation. The documentation was missing from the STAR research system. One study at Bellevue, there was an approved protocol modification that instituted the use of a professional transcriber for audio interviews, but we could not find any documentation that the budget was revised to reflect the increased cost for the transcriber. At one study at Bellevue, the study was listed as active in the STAR database, but upon review it was noted that the principal investigator had already closed the study with the IRB.

Then one study at Morrisania it was noted that the IRB continuing review approval date was incorrect in the STAR system.

With respect to training on OP 180-9, we noted after interviewing at least 35 staff members that although the PIs were familiar with the IRB approval process, most were not familiar with the full scope of Operating Procedure 180-9. Most of the PIs that were interviewed were unable to speak to the increase in the research record retention that is required under 180-9 or with respect to the IRB continuing review process and procedures as they are out lined under 180-9. Many of the PIs were unaware of the training that was given by the Office of Research Administration or were not available at the time and date that the training was offered at their facility.

Our recommendation is that formal training on new skill requirements that are required under 180-9 should be implemented to cover the facility research coordinator and the facility research committees. Management's response to that is that the Office of Research Administration will continue to work to develop a standard process across the System including training and education of these individuals.

Mr. McNulty asked if management would like to add anything to the response.

Dr. Jones answered that what is happening mostly in this facility is most of the PI's look at H + H as an afterthought for example. For a PI there's a two-step process. You have an IRB approval. IRB approval example is NYU. NYU is the IRB determiner, so you have approval from NYU. It's also incumbent upon that PI to also input that information or load that information into our system. So the question becomes, my challenge since I have been here for almost three years now is how will I be able to change this culture that if you do it for the IRB, it's just a rule of thumb. If you do it for IRB, remember also to do it for H+ H.

Dr. Allen added that I think this is a very important point, how do we get our message to all our facilities and all our providers. We will be using our chief medical officer council to get this message across as well as our various clinical councils so that there are multiple venues for training, so it's not just what's been happening. The Central Research Administration has been going ot the facilities and doing one-on-one investigation or training, and that's not sufficient, so we have to use all of our council, the CMO council, the CNO council, the clinical council to re-enforce this message.

Mr. Page asked if there is some procedural way of linking when you go to this first approval with what you think is the agency that you are actively working with that i n the process of getting the approval there if automatically requires you to get the approval from H + H at the same time.

Dr, Allen responded that I think we have to look to see if that can automatically happen. I'm not sure today if we can match them and automatically link them, but it is certainly worth investigating. Short of that we just have to mandate if you are not in our system, we can't do it.

Mr. Page stated that it would be wonderful if we can somehow short circuit the administrative loops to that it just has to happen together.

Dr. Allen said that we will look into that.

Mr. McNulty continued and stated that the review of the study documentation and related interviews demonstrated basic understanding of the requirements for completing the research process. However, it was clear that the STAR submission process is still somewhat confusing to many of the users.

We documented the following findings; that there were user errors that affected the integrity of the data in the system including without limitation error in the funding and budgetary numbers were identified; incorrect IRB documents were uploaded in the STAR system; staff showed studies as active although they were no longer active in the system; and that the contractual information was always available.

Management's response to these findings is that there will be improvement that will be made to the STAR system going forward to better control these user errors.

Mr. McNulty asked if management want to add anything to that?

Dr. Allen answered that I will just say as we mentioned earlier with Mr. Telano's findings that we have to modify the STAR system to allow that the required fields are in fact in there to be completed and that they are completed in a timely fashion.

Mr. McNulty said that we also looked at whether or not there was a standard process in place to ensure that, for example, if we perform certain ancillary tests during research that those tests were covered and reconciled, and we received proper payment for these tests. Although it seemed that there were familiarity with the process, there was no standard process throughout the system. So our recommendation is that there be a standardized system for tracking and reconciling expenses and revenue as required by OP 180-9 and to implement systems to ensure that all billable services are identified and all payments are reconciled.

Management's response was that a new workflow was being developed by the Office of Research Administration in consultation with Finance as necessary that will readily resolve these particular issues.

Dr. Allen commented that we agree with that recommendation. This is going to require a close alliance with Finance that there is a specific clinic code to identify a research subject and ancillaries attached to his visits in QuadraMed. There is a clinic code reconciling the financial on a regular basis.

Mr. McNulty stated that I would just like to add in closing, Dr. Allen and I spoke about research going forward, and I am going to meet with all the medical directors in March and have a presentation with these and go through the high-risk areas and make sure they are familiar with how to avoid those risk areas.

Dr. Allen stated that just for the Committee, I think the H + H research has been going on for a long time. We do encourage research because that is where we learn what the cutting edge and progressive, new clinical modalities are. In my tenure at H + H, we went through multiple ways of tracking research. This is a new system that we are using. We would not expect every provider to know every page of the OP 180-9, but at least the essence of the crucial regulatory requirement needs to be known by everybody.

Mr. Telano continued with the review of pharmacy inventory control at the Jacobi facility and asked for the representatives to approach the table and introduce themselves. They did as follows: Christopher Mastromano, Chief Operating Officer; Joseph D'Agostino, Director of Pharmacy; Manfred Pomps, Assistant Director of Pharmacy.

Mr. Telano reported that we did an announced count of 111 items and we found initially that 42 percent of the items had discrepancies, and the primary reason was that no one individual within the department was assigned the daily responsibility to input inventory activity. Once the outstanding paperwork was accounted for, the discrepancies were reduced to 14 percent. Also in-line with that because they are not doing things on a daily basis, we found that there were still 10 controlled substances, which are narcotics, still improperly included in the pharmacy stockroom inventory system although physically they were in narcotics storage area. We also noted that part of the issue is that the pharmacy department does not performed periodic inventory counts throughout the fiscal year to ensure the accuracy of their inventory.

Mr. D'Agostino responded that the root of the problem is with the cycle counts being done. Initially our view of what the inventory counts would be the full inventory, and doing a full inventory tends to be a little difficult in the pharmacy because it would require not closing down the stockroom, not being able to give out any kinds of medications during that period. It would have to take place during off hours or on weekends. That becomes an issue. Our auditors did point out, which is very helpful, that doing a cycle count, which is a smaller amount of drugs, maybe 20, 25 drugs per week but weekly, would help satisfy the inventory. It would help keep us right on the money.

If those cycle counts picked up on the fact that the controlled substances -- while they were physically in our narcotic room and there was no issue with chain of custody with the narcotics, we would have caught on the cycle counts that they were misfiled or miss-documented in the stock room -- that would have taken care of the second issue of controlled substances. He reemphasized that controlled substances are received from our wholesaler, they're instantly placed in the narcotic room and put into the C11Safe inventory system. Narcotic inventories are conducted weekly in that separate system; therefore, at no time was that an issue. It was just a clerical error where we charged it to the main stockroom.

As far as the first item, we experienced some issues -- counts that were not up to date. A good proportion were reconciled, and the last three items showed that they were within the pharmacy area. Pre packing is done in the automated pharmacy system, and we were able to show through the logs that those medications were accounted for.

Mr. Pompa stated that with regard to the narcotics order, three of those items were selected on the surprise audit and the other seven were found when I pulled out the purchase order, which showed that all the items, all ten items made it into the narcotic room, were in the C11Safe, were all accounted for physically. It was a clerical error that the items ended up in the regular stock room. One of the items that came up in the findings was a refrigerated item. The day prior to the surprise audit, a major refrigerator in our stock room went down, so all those items needed to be removed from that refrigerator and brought into an outside main floor refrigerator. They were all put into totes and were sealed, and at the time when that item came up for counting, it was in the main refrigerator in a tote sealed. The paperwork was not filed because those items all were returned back into the stock room once the refrigerator was fixed.

Mr. D'Agostino said that what are we doing to correct things is to the charge has to be done on a timely basis. We are striving to get that done. We are training staff to have a clerical person that we are training to do charge outs on a timely basis. The goal is to have the charge out done by the end of the day on that day. Our cycle counts have been instituted, and we are going forward with that.

Mr. Page asked that in trying to picture how this works, when you are moving stock in and out, is it basically each item is done on a single slip, and what you are talking about is actually going back through a pile of slips and entering them into the system?

Mr. D'Agostino answered not each item, but an order will be handwritten because it is still manual. We do not have bar coding or anything like that within the facility, everything is done manually. Someone has to go through those manual slips and requisitions and keypunch them into e-Commerce.

Mr. Pompa added that we are counting the items coming in, and it would be nice to import everything into the system as well as in terms of removing items from the system so that it tags all out.

Mr. Martin commented that ERP is actually going to take care of a lot of this, and I think we are close. We are looking at 2018, but I think we are going to try to escalate that and maybe even implement it a little bit sooner. It is the way the rest of the world actually operates. That is why it's so important.

Mr. Telano stated that if there are no further questions, I'll move on to my final review. It was of a medical/surgical inventory controls at North Central Bronx. He asked for the representatives come to the table and introduce themselves. Mr. Chris Rust introduced himself as Director of Operations and Support.

Mr. Telano reported that during our review, we conducted an unannounced count of 105 items and revealed a discrepancy rate of 57 percent. We recommended that inventory cycle counts as noted in the previous audit be initiated, and this was implemented during the course of the audit. We also noted that when items are brought to the patient units, the head nurse or the designee is not signing the form acknowledging receipt of those items that they were put in the storeroom properly.

Lastly we noted that there was sometimes excess items that were in the storerooms within the patient units that were brought back down to the warehouse area. These items were already input into the inventory system and removed. However, instead of re-inputting them into the inventory system, they were kept in a separate shelf area called the "Free Picking Area", so they were not accounted for in the inventory system, and they were in a separate area.

Mr. Rust stated that North Central have had challenges specifically with internal controls and managerial oversight. This was picked up in the report and with that as a result really a chain of custody of moving these supplies. When supplies were picked, they were moved to the floor without supervising checking. They were delivered on the floor without getting a signature from a head nurse or charge nurse. Any extra supplies that would come down as Mr. Telano said, they were not keyed back into the system. We have revamped our internal controls to make sure that this does not happen moving forward When supplies are picked, they were actually checked by the supervising stock worker to make sure that what was picked was accurate. Those supplies are then moved up to the units in our internal controls.

Our procedure now is that the head nurse will actually check for the receipt. They are not there to necessarily count every item. There is a chain of custody. When those sheets get returned, those sheets are then reviewed by the supervising stock worker. If there are any supplies that are in excess, they come back to Materials Management. They are now keyed out and returned back into the e-Commerce system. With our internal controls, we have folders of this information so that again I go down and check from time to time and make sure that we are, that our internal controls in compliance and we are doing cycle counts to make sure that our inventory is accurate.

Mr. Telano asked if there were any questions and then stated that that concludes his presentation.

Mr. McNulty reported on CMS Medicare Parts C and D General Compliance Training required under Contractual Obligations with Medicare Advantage Organizations. Pursuant to CMS regulations, Medicare Advantage Organizations (MAOs) are required to adopt and implement an effective compliance perform designed to prevent, detect and correct instances of noncompliance with CMS requirements and fraud, waste and abuse. Examples of MAOs include MetroPlus, Aetna, Fidelis, GHI and HealthFirst, all of which have provider agreements with the System.

In our role, the System's role under contract with these MAOs, we are required to provide the Medicare Part C and D training that we are considered First-Tier, Downstream or Related Entity. One of the requirement elements of the MAO compliance program is the establishment and implementation of effective compliance training and education. To that end, in December of 2016, the Office of Corporate Compliance distributed via e-mail the CMS Compliance Training materials for all System workforce members and to all System business partners to ensure that we meet the MAO training requirements as established by CMS. We were able to distribute them via e- mail because that is one of the mechanisms that CMS says is an acceptable way to train our work force. Moving forward, we will add the CMS trainings to our annual compliance training so that all Board members and all workforce members, health care professionals and physicians receive that CMS training through that mode and methodology.

Moving on to monitoring of excluded providers, the Office of Corporate Compliance screens all workforce members and all vendors under the OIG exclusion list, the Office of the Medicaid Inspector General exclusion list and the system-wide exclusion list under the Department of Health and Human Services to ensure that we don't have any employee that is excluded from participating in federal health care programs. We also searched the list of the Office of Foreign Asset Control to ensure that we do not have any workforce members or vendors upon that list, and that list is designed to halt terrorist and other illegal funds from being circulated throughout the nation.

We found with respect to our exclusion survey on December 23, 2016, the OCC was informed that the social worker assigned to provide NYC Health + Hospitals counseling under the System's Employee Assistance Program was excluded by OMIG in August of 2015 . The excluded individual was not on the OIG list but only the OMIG exclusion list. We at that particular time suspended the services provided by that particular social worker, and just note that that social worker was employed by New York City Department Office of Labor Relations and was assigned to assist in the counsel of NYC Health + Hospitals employees pursuant to a contract between the System and OLR. This employee was able to have their name removed from the exclusion list, and the employee has returned to provide services to NYC Health + Hospitals in January. The expenses related to this excluded individual is going to be reflected in a non-reimbursable cost on our applicable cost report, and therefore don't envision that there will be any self-disclosure required, but we are under counsel of Legal Affairs to make that final determination.

There was an OIG and SAM exclusion of a Lincoln Hospital Recovery Center acupuncturist. We noted that the acupuncturist was on the System for Award Management exclusion list. It appeared that this individual was placed on that list from prohibited conduct that occurred nearly 30 years ago. This excluded individual worked from December 27, 2016, to January 11, 2017. When we learned of the exclusion, he was placed on 75-day suspension to allow this individual time to be removed from the exclusion list. We have determined that these costs are not billable costs and therefore do not believe there will be any over payments, but again we are consulting with Legal Affairs with respect to that, and hopefully the individual will be able to have their name removed from the list.

We also learned about an OMIG exclusion at Metropolitan Hospital Center, and that involved a volunteer. We learned about it on January 20, 2017. The volunteer appeared on the OMIG exclusion list effective November 27, 2016. The volunteer was informed that he cannot work in the capacity of a volunteer for Health + Hospitals while on the exclusion list, and we are now evaluating whether or not we will have to make a self-disclosure with respect to that volunteer.

We are going to move onto some updates on past exclusions that we had previously reported to the Audit Committee.

In February 2016, we informed the Audit Committee about a Kings County nurse's exclusion from Medicaid. The nurse was placed on inactive status without pay effective December 30, 2015, and her employment was terminated in January. On February 16, 2016, we sent a self-disclosure letter to OMIG with respect to how much we owed OMIG back for the services that were provided by this excluded individual. OMIG came back to us in September and informed us that they denied our disclosure as far as the amount that we came up with, and they sent us a spreadsheet on how they want us to calculate the amount, so then we recalculated the amount and sent them a second self-disclosure in December 2016, and we are waiting to hear back from OMIG at this particular time.

OIG and SAM exclusion list of a Woodhull Hospital nurse required self-disclosure. In December 2016, the Audit Committee was advised about a Woodhull nurse who appeared on the OIG and SAM exclusion list effective October 20, 2016 and then a nurse subsequently appeared on OMIG's exclusion list effective in November. We placed the nurse on unpaid administrative leave and advised the nurse that she had 75 days to resolve the exclusion issue or that she would be separated from services. Pursuant to OMIG and OIG protocols, we sent self-disclosure letters to OMIG on January 5th and OIG on January 10th. The refund check mailed to OMIG was for $3,537.89, and a check for $1,385.17 was sent to National Government Service, which is a CMS contractor. OMIG had contacted me this week. They had a dispute on the way that we did the calculations. They changed the form letter they recently gave us to a new form letter, so they sent the check back and are now recalculating the amount owed to OMIG. With regard to the disclosure we made to National Government Services, we haven't heard back from them yet, but we will follow up with them.

In the fourth quarter of 2016, October 1, 2016, to December 31, 2016, we received 39 complaints relating to privacy incidents that was entered into our ID experts RADAR Incident Tracking System. Of these we found that ten were violations of HIPAA policies and procedures and four were breaches of protected health information, and we sent breach notification to those particular individuals.

An overview of some of these breaches:

- One involved a business associate that sent information wrongly to one patient to another patient, so we determined that that was a breach, and we had to send notification to that particular patient.
- This is a more serious incident and involved a System employee being treated at Metropolitan and another System employee informing other individuals at Metropolitan that that individual was being treated there. We sent out a breach notification with respect to that, and I'm following up with HR at that facility to make sure there is disciplinary action implemented for that particular employee.
- At Lincoln Medical and Mental Health Center in November 2016, we had an incident involving a patient that received an appointment slip that was intended for another patient. We sent out a breach notification to that particular patient.
- At Kings County Hospital Center in December 2016, we had a social worker who erroneously sent a fax to the wrong fax number. We are strengthening our policies and procedures with respect to that particular area and making sure that we are retraining. Whenever you send a fax, obviously you want to make sure that you have the right number and that you have a cover page on the fax. That was another thing. There was no cover page on the fax that said if this goes to the wrong recipient, please do not open it and send it back and make sure somebody is on the other end of the fax to receive the fax. The individual was retrained, and we are going to make sure that our policies and procedures in that particular area is strengthened.

Moving on to the compliance report for the fourth quarter of 2016, we received 88 compliance-based reports. We received no Priority A reports, which are reports that require immediate attention. We had 34 Priority B reports and 54 Priority C reports.

What is surprising is that we are receiving a large number of our reports now by e-mail, so 20 percent of the reports we received were by e-mail, and 38 percent were received by our compliance hotline, so we welcome this new way we are starting to receive reports, but we also remind the workforce that if they want to send a report anonymously that the hotline is the way to go about that.

This is the final item on the report, One City Health/DSRIP Compliance Update -- DSRIP Compliance Training and Education and Assessment of the Compliance Integrity of OneCity Health Partners. In late December the Office of Corporate Compliance sent a memorandum to all performing providers in the NYC Health + Hospitals-sponsored OneCity Health Performing Provider System reminding them of their Delivery System Reform Incentive payment program compliance training and education requirements. DSRIP compliance training and education requirements under New York State law and Office of Medicaid Inspector General, they require OneCity Health as a PPS lead to ensure that DSRIP funds are used appropriately.

We provided the DSRIP partners with a compliance training and education PowerPoint that they could use if they wish to use. The PowerPoint covered all the DSRIP compliance training requirements and the eight elements under the DSRIP compliance program. We also sent in February attestation to all DSRIP partners where they would have to certify to us, (1) if they distributed the compliance training and education to all their workforce members; (2) if they distributed our Principles of Professional Conduct to all their workforce members and that they adhere to the same; (3) whether or not they were certified under Part 5 21 of the Medicaid regulations for an effective compliance program; and, (4) whether or not they certified to OMIG if they comply with the Deficit Reduction Act of 2005, which requires them to have written policies and procedures under State False Claims Act, Federal False Claims Act and any other areas related to state laws for whistle blower protections and fraud, waste and abuse.

An attestation was sent out on February 2, 2017, to over 200 partners. We received back about 12 of the attestations to date a week later, and we are very pleased that 11 out of the 12 are certified with the Office of the Medicaid Inspector General for all effective compliance programs and in compliance with the Deficit Reduction Act. That is our way of doing a risk assessment to see which partners would be more vulnerable with respect to compliance and integrity. If they are already certified, then those providers obviously would be low-risk provides.

Random audits of the different partners will be conducted to make sure that they have these policies and procedures in place in the upcoming months, and we have a webinar with the partners on next Tuesday to go over the attestation just in case there are any questions.

Mr. McNulty stated that that concludes my report.

Mr. Page thanked him.

There being no further business, the meeting was adjourned at 2:16 P.M.

NYC HEALTH + HOSPITALS

AUDIT COMMITTEE OF THE NYC HEALTH + HOSPITALS BOARD OF DIRECTORS

Corporate Compliance Report

April 4, 2017

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I. Follow-Up on Human Subject Research Protections Program Activities

Background

1) During the February 2017 Audit Committee of the Board of Directors (the "Audit Committee" or the "Committee") meeting, the Office of Corporate Compliance ("OCC") briefed the Committee on its audit review findings as they related to the System's human subject research activities. The OCC reported several deficiencies in the System's compliance with (and System personnel awareness of) Operating Procedure ("OP") 180-9 (*NYC Health + Hospitals Human Subject Research Protections Program Policies and Procedure*s).

2) In response to these findings, the OCC has begun to work closely with the Office of Medical and Professional Affairs ("OMPA") and Office or Research Administration ("ORA") to further develop the System's Human Subject Research Protections Program.

3) On March 22, 2017 the OCC provided a PowerPoint Presentation on the System's Human Subject Research compliance activities at the System's Chief Medical Officers' meeting held in the boardroom at 125 Worth Street, New York, NY. The PowerPoint Presentation covered, in pertinent part, the following topics:

- Background and development of OP 180-9;
- The responsibilities of the Facility Medical Directors as they relate to research;
- The responsibilities of the Principal Investigators as they relate to research;
- The OCC's Compliance Review of the System's research activities; and
- The development of a Human Subject Research Quality Improvement Program.

4) In the upcoming months, .the OCC, working with the OMPA, ORA, and Office of Legal Affairs, will provide a PowerPoint Presentation on OP 180-9 before the System's Research Council in the upcoming months. The OCC will also be developing an audit protocol for System facilities that are involved with human subject research to perform routine internal evaluations of their research activities with the goal of ensuring continual compliance with applicable research regulations, as well as compliance with OP 180-9.

5) The OCC is also working with all of the aforementioned offices to develop the System's quality assurance activities as they relate to clinical research.

NO FURTHER TEXT ON THIS PAGE

II. Privacy Incidents and Related Reports

Background

1) The Office of HIPAA Privacy and Security within the OCC is responsible for reviewing, investigating, and responding to potential and confirmed breaches of Protected Health Information ("PHI").

Reportable Privacy Incidents for the Fourth Quarter of Calendar Year 2016 (October 1, 2016 to December 31, 2016 – hereinafter "4th Quarter"))

2) During the period of October 1, 2016 to December 31, 2016, thirty-nine (39) complaints were entered in the ID Experts RADAR Incident Tracking System. Of the 39 complaints entered in the tracking system eleven (11) were found after investigation to be violations of the System's HIPAA Privacy Operating Procedures; seven (7) were determined to be unsubstantiated; fourteen (14) were found not to be a violation of the System's HIPAA Privacy Operating Procedures; and seven (7) are still under investigation.

- Of the 11 incidents confirmed as violations, 5 were determined to be breaches. A total of 6 individuals were affected by the 5 confirmed breaches.

Breach Defined

3) A breach is an impermissible use, access, acquisition or disclosure (hereinafter collectively referred to as "use and/or disclosure") under the HIPAA Privacy Rule that compromises the security and privacy of PHI maintained by the Corporation or one of its business associates.[1]

4) Pursuant to 45 CFR § 164.402 [2], the unauthorized access, acquisition, use or disclosure of PHI is presumed to be a breach unless NYC Health + Hospitals can demonstrate that there is a low probability that the PHI has been compromised based on the reasonable results of a thorough risk assessment, that is completed in good faith, of key risk factors.[2]

Factors Considered when Determining Whether a Breach has Occurred

5) Under HIPAA regulations, at a minimum the following four key factors must be considered to determine whether there is greater than a low probability that a privacy and/or security incident involving PHI has resulted in the compromise of such PHI:[3]

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;

[1] 45 CFR § 164.402 ["Breach" defined].
[2] *See* 45 CFR § 164.402[2]; *see also* 78 Fed. Register 5565 at 5643 and 5695 [January 25, 2013]
[3] *See* 45 CFR § 164.402 [2][i-iv].

- The unauthorized person who used the protected health information or to whom the disclosure was made;
- Whether the protected health information was actually acquired or viewed; and
- The extent to which the risk to the protected health information has been mitigated.

Reportable Breaches in the 4th Quarter

6) As stated above, there were 5 reportable breaches in the 4th Quarter. Below is a summary of said breaches:

- *Elmhurst and Jacobi Hospitals – October 2016*

Incident: The incident occurred when Cerner, a NYC Health + Hospitals business associate, encountered a printing issue when preparing billing statements to be sent to our patients. The error caused the last page of a patient's billing statement to be included with a billing statement sent to another patient. The error caused the PHI of two patients, one from Elmhurst and one from Jacobi, to be disclosed to a patient from another covered entity. The PHI included patient name, statement date, guarantor account ID, charges, date of service, and description of service. Cerner notified NYC Health + Hospitals of the incident and corrected the error.

Breach Determination: Based upon the facts found during the investigation, the incident was determined to be a breach. Notification was sent to the affected individuals on December 16, 2016.

Mitigation: To mitigate the error, Cerner updated their quality check process to include a manual record of the completion of a quality checklist by operators for any jobs that experience errors during printing. Cerner also retrained the operators by providing written reminders of the quality checkpoints at each operator station in addition to having the quality checkpoints posted in common areas.

- *Metropolitan Hospital Center – November 2016*

Incident: The incident involved an employee disclosing the inpatient status of a patient, also an employee in the HIM department, to the patient's coworkers. The patient was admitted to Metropolitan Hospital. The employees/coworkers then attempted to visit the unit the patient was located on without proper authorization. The employees were prevented from seeing the patient by nursing staff.

Breach Determination: Based upon the facts found during the investigation, the incident was determined to be a breach. Notification was sent to the affected individual on December 23, 2016.

Mitigation: The employee who disclosed the patient's information is currently facing disciplinary action. The employees who attempted to visit the patient were retrained on HIPAA patient privacy rights as well as NYC Health + Hospitals policies regarding patient privacy.

- *Lincoln Medical Center – November 2016*

Incident: The incident involved a patient receiving an appointment slip intended for another patient. The appointment slip contained PHI such as patient name, medical record number, clinic name, and appointment information. The patient presented to the clinic for the appointment when an employee noticed the error and collected the slip. The appointment slip was not given back to the incorrect patient.

Breach Determination: Based upon the facts found during the investigation, the incident was determined to be a breach. Notification was sent to the affected individual on January 17, 2016.

Mitigation: The clinic employees received retraining on the requirements to check for two forms of identification prior to releasing any confidential documents to our patients.

- *Kings County Hospital – December 2016*

Incident: The incident involved a social worker sending a fax, which included the discharge summary of one patient, to the workplace of a family member of another patient. The social worker also failed to include a fax cover sheet along with the documents that were faxed. Upon discovering that she had received the information of another patient, the recipient contacted the Patient/Guest Relations department at Kings to alert them of the error. The recipient then proceeded to destroy the fax and confirmed as such with Patient/Guest Relations. The discharge summary included PHI such as the patient's name, date of birth, medical record number, treatment information, medication, and diagnosis.

Breach Determination: Based upon the facts found during the investigation, the incident was determined to be a breach. Notification will be send to the affected individual on February 7, 2017.

Mitigation: The employee was required to attend HIPAA retraining led by the Facility Privacy Officer. Topics covered during the retraining included a review of HIPAA and PHI, accidental and unintentional disclosures, procedures for faxing confidential information, HIPAA OP 250-19 Transmission Security, HIPAA Do's and Don'ts, and tips on safeguarding patient privacy. The director of social work also requested that the FPO provide in-service to the entire department covering the same topics in the one-on-one training. Lastly, a new fax cover letter was developed

which now includes a statement on re-disclosure at the bottom of the fax. Formal disciplinary action by Human Resources was not requested by the employee's supervisor as the employee has no record of any other similar HIPAA incidents. A policy on secure faxing is being drafted as well.

- *Bellevue Hospital – December 2016*

Incident: The incident involved an employee accessing the record of a patient on multiple occasions, which was confirmed by an access audit. The employee was the mother of the patient and admitted to accessing the chart to review the treatment and medications being provided to the patient.

Breach Determination: Based upon the facts found during the investigation, the incident was determined to be a breach. Notification was sent to the affected individual on February 17, 2017.

Mitigation: The incident was referred to Bellevue Human Resources and the employee will be facing possible disciplinary action.

III. Monitoring of Excluded Providers

Overview of Regulatory Requirements

1) As the Audit Committee has been previously advised, Federal regulations underscore that "no payment will be made by Medicare, Medicaid or any of the other Federal health care programs (*e.g.*, Medicaid, Medicare) 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." [4] New York State (the "State") has similar billing prohibitions on the use of 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." [5]

Responsibilities of the System for Sanction List Screening

2) To adhere to these regulations, and consistent with the recommendations of the

[4] 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).
[5] *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.)

NYS Office of the Medicaid Inspector General ("OMIG") [6] and the United States Department of Health and Human Services Office of the Inspector General ("OIG"), each month the Office of Corporate Compliance ("OCC") confirms that none of the NYC Health + Hospitals' (the "System") workforce members (*e.g.*, employees, board members, affiliates, personnel, volunteers, and medical staff members), vendors, and DSRIP partners are excluded from participation in Federal healthcare programs such as Medicaid and Medicare.

Office of Foreign Asset Control ("OFAC") Screening

5) In addition, to ensure business is not conducted with terrorist organizations or other sanctioned entities, all United States incorporated entities are required to comply with regulations of the Office of Foreign Asset Control ("OFAC"). [7] Therefore, the OCC also screens all NYC Health + Hospital Workforce members, vendors and DSRIP partners against all OFAC databases designed to halt terrorist and other illegal funds from circulating.

Exclusion and Sanction Screening Report for November 29, 2016 through February 6, 2017

6) Since the OCC last reported to the Committee on the System's excluded provider activities in February 2017, there have been no excluded providers to report.

IV. Summary of Compliance-Related Reports for the Fourth Quarter of Calendar Year 2016

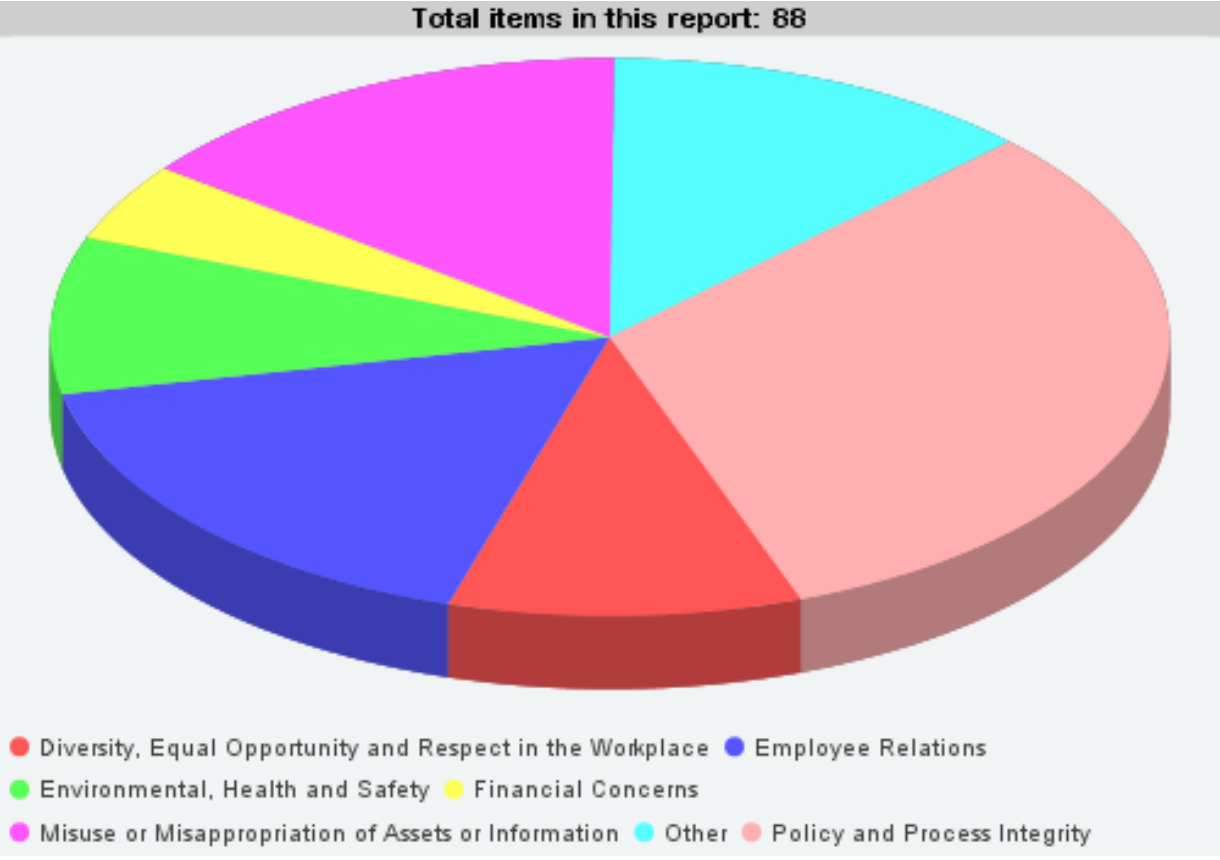
1) For the fourth quarter CY2016 (October 1, to December 31, 2016) there were 88 compliance-based reports of which 34 (38.6%) were classified as a Priority "B"[8] and 54 (61.4%) were classified as a Priority "C" reports. There were no Priority "A" reports. For purposes here, the term "reports" means compliance-based inquiries and compliance-based complaints. The breakdown of 4th quarter reports by subject, source and allegation are as follows:

[6] 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.]

[7] *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.]

[8] 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.

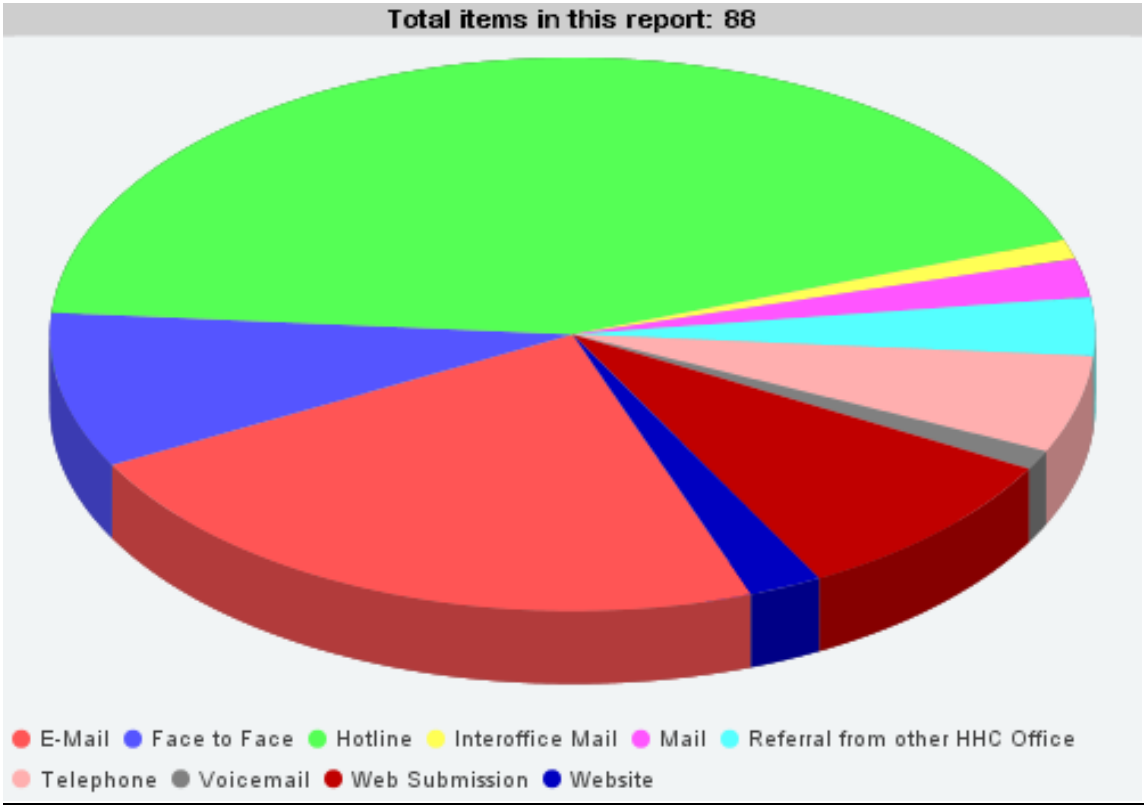
A. By Subject



Distribution of Reports by Subject

Diversity, Equal Opportunity and Respect in the Workplace	9.0 (10.2 %)
Employee Relations	15.0 (17 %)
Environmental, Health and Safety	8.0 (9.1 %)
Financial Concerns	4.0 (4.5 %)
Misuse or Misappropriation of Assets or Information	13.0 (14.8 %)
Other	11.0 (12.5 %)
Policy and Process Integrity	28.0 (31.8 %)
Totals	88.0 (100%)

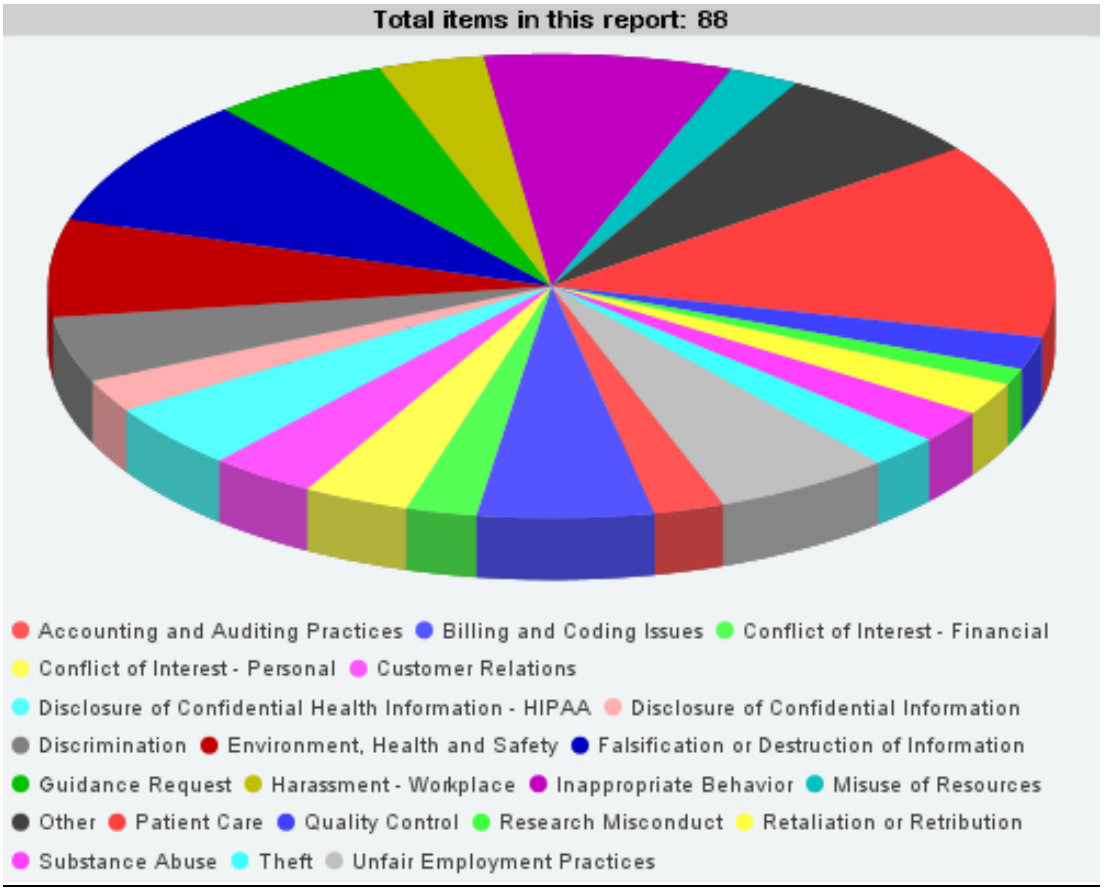
B. By Source



Distribution of Reports by Source

E-Mail	20.0 (22.7 %)
Face to Face	8.0 (9.1 %)
Hotline	38.0 (43.2 %)
Interoffice Mail	1.0 (1.1 %)
Mail	2.0 (2.3 %)
Referral from other HHC Office	3.0 (3.4 %)
Telephone	5.0 (5.7 %)
Voicemail	1.0 (1.1 %)
Web Submission	8.0 (9.1 %)
Website	2.0 (2.3 %)
Totals	88.0 (100%)

C. By Allegation



Distribution of Reports by Allegation

Accounting and Auditing Practices	2.0 (2.3 %)
Billing and Coding Issues	5.0 (5.7 %)
Conflict of Interest - Financial	2.0 (2.3 %)
Conflict of Interest - Personal	3.0 (3.4 %)
Customer Relations	3.0 (3.4 %)
Disclosure of Confidential Health Information - HIPAA	4.0 (4.5 %)
Disclosure of Confidential Information	2.0 (2.3 %)
Discrimination	4.0 (4.5 %)

Environment, Health and Safety	6.0 (6.8 %)
Falsification or Destruction of Information	8.0 (9.1 %)
Guidance Request	5.0 (5.7 %)
Harassment - Workplace	3.0 (3.4 %)
Inappropriate Behavior	7.0 (8 %)
Misuse of Resources	2.0 (2.3 %)
Other	6.0 (6.8 %)
Patient Care	12.0 (13.6 %)
Quality Control	2.0 (2.3 %)
Research Misconduct	1.0 (1.1 %)
Retaliation or Retribution	2.0 (2.3 %)
Substance Abuse	2.0 (2.3 %)
Theft	2.0 (2.3 %)
Unfair Employment Practices	5.0 (5.7 %)
Totals	88.0(100%)

V. Compliance Requirements for an Effective Compliance Program under the Medicare and Medicaid Programs Reform of Requirements for Long-Term Care Facilities ("Final Rule")

Background

OIG Compliance Program Guidance for Nursing Facilities (2000)

1) On March 16, 2000 Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") first published guidance about the creation and implementation of nursing facility compliance programs.[9] The OIG 2000 guidance describes "Seven Basic Compliance Elements" for a comprehensive compliance program. A summary of these seven elements are as follows:

- **Element # 1** - The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that promote the nursing facility's commitment to compliance (e.g., including adherence to the compliance program as an element in evaluating managers and employees) and address specific areas of potential fraud and abuse, such as claims development and submission processes, quality of care issues, and financial arrangements with physicians and outside contractors;

[9] See *OIG Compliance Program Guidance for Nursing Facilities*; 52 Fed. Reg. 14289 (2000).

- **Element # 2** - The designation of a compliance officer and other appropriate bodies (*e.g.*, a corporate compliance committee) charged with the responsibility for developing, operating and monitoring the compliance program, and who reports directly to the owner(s), governing body and/or CEO;

- **Element # 3** - The development and implementation of regular, effective education and training programs for all affected employees;

- **Element # 4** - The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process, such as a hotline or other reporting system, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistle blowers from retaliation;

- **Element # 5** - The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

- **Element # 6** - The development of policies and procedures addressing the nonemployment or retention of excluded individuals or entities and the enforcement of appropriate disciplinary action against employees or contractors who have violated corporate or compliance policies and procedures, applicable statutes, regulations, or Federal, State, or private payor health care program requirements; and

- **Element # 7** - The development of policies and procedures with respect to the investigation of identified systemic problems, which include direction regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action, repayments, and preventive measures.[10]

OIG Supplemental Compliance Program Guidance for Nursing Facilities (2008)

3) To better describe the necessary components of an effective compliance program, the OIG also published supplemental guidance for nursing facility compliance programs on September 30, 2008. The 2008 guidance did not change the seven required nursing home compliance program elements. Rather, the 2008 guidance focused on the "significant changes in the way nursing facilities deliver, and receive reimbursement for, health care services, as well as significant changes in the Federal enforcement environment and increased concerns about quality of care in nursing facilities, which continues to be a high priority of OIG."[11]

[10] Department of Health and Human Services Office of Inspector General ("OIG") *Publication of the OIG Compliance Program Guidance for Nursing Facilities*; 65 Fed. Reg.14289, 14291, § II(A) (2000)
[11] *OIG Supplemental Compliance Program Guidance for Nursing Facilities*; 73 Fed. Reg. 56832, 56833 (2008)

Medicare and Medicaid Programs Reform of Requirements for Long-Term Care Facilities ("Final Rule")

5) The Affordable Care Act ("ACA") of 2010 required the development of regulations for compliance and ethics programs in nursing facilities. After providing for those requirements and reviewing feedback from nursing facilities in 2015 by way of the Proposed Rule[12], the Final Rule was published in October 2016.[13] The reorganized standards set forth in the Final Rule better reflect the advances in the theory and practice of service delivery and safety, the implementation requirements of the ACA and incorporate the comments provided from nursing facility reviews of the Proposed Rule. The Final Rule strengthens the understanding of the minimum standards that long-term care ("LTC") facilities must meet in order to participate in the Medicare and Medicaid programs.[14]

6) Final Rule changes "ensure that regulations coincide with current clinical practice and allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services at these facilities."[15]

7) The Final Rule is similar to prior OIG guidance provided in 2000 and 2008 and expands the requirements for compliance and ethics programs from seven to eight elements. The requirements for compliance and ethics programs in the Final Rule is codified at 42 CFR § 483.85 and includes the following eight elements[16]:

- **Element # 1** - Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

[12] *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*; 81 Fed. Reg. 42168 (2015).
[13] *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care* Facilities; 81 Fed. Reg. 68688 (2016).
[14] *Finale Rule to Reform the Requirements for Long-Term Care Facilities*, https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-10-27-LTC-Presentation.pdf, [Centers for Medicare & Medicaid Services, October 27, 2016].
[15] *Medicare and Medicaid Programs Reform of Requirements for Long-Term Care Facilities* ("Final Rule") 81 Fed. Reg. 68688, 68691, § I(C) (2016)
[16] 42 CFR § 483.85(c).

- **Element # 2 -** Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

- **Element # 3** - Sufficient resources and authority to the specific individuals designated to reasonably assure compliance with compliance and ethics standards, policies, and procedures.

- **Element # 4** - Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

- **Element # 5** - The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

- **Element # 6 -** The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

- **Element # 7** - Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

- **Element # 8** - After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

8) The Final Rule requires additional components for operating organizations with five or more facilities. In addition to the eight required components listed above, operating organizations with five or more facilities must include three additional components[17], specifically:

- **Additional Component # 1** - A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in the Final Rule at 42 CFR 483.95(f).[18]

- **Additional Component # 2** - A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

- **Additional Component # 3** - Designated compliance liaisons located at each of the operating organization's facilities.

VI. DSRIP Compliance Attestation of OneCity Health Partners

Background

1) As a 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."[19] To satisfy its compliance obligations as the PPS Lead and to fulfill the requirements of the aforementioned 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.

As more fully described below, all OneCity Health Partners were, accordingly, asked to disclosed within the form of the Attestation information about DSRIP Compliance training; adoption of

[17] 42 CFR 483.85(d)
[18] 42 CFR 483.95(f) - Compliance and ethics. The operating organization for each facility must include as part of its compliance and ethics program, as set forth at § 483.85— (1) An effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program. (2) Annual training if the operating organization operates five or more facilities.
[19] 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

NYC Health + Hospitals Principles of Professional Conduct or comparable code of conduct; and annual OMIG compliance certifications.

The Attestation 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: (a) disclose the status of their completion of DSRIP compliance training (a training PowerPoint had previously been previously provided to the Partners); (b) acknowledge 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; and (c) provide 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.

4) The two OMIG compliance certifications referenced in paragraph 2 of this section are as follows:

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

5) In addition to the above, the OCC participated in an OneCity Health webinar on February 14, 2017 to answer Partner questions regarding the Attestation and to remind the Partners that the Attestations were due on March 20, 2017.

6) 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

7) Of the 228 Attestations distributed to Partners, 91 have been returned to the OCC.

8) Of the 91 Attestations that were returned, 91 have certified completion of meeting their DSRIP training and education requirements either through in/person/live compliance and education training; incorporating the training content into existing compliance training

computerized modules (e.g. automated online training); or distributing the training materials to workforce members involved or associated with or otherwise affected by the DSRIP program.

- Of the 91 Attestation that were returned, 91 have adopted the POPC or their own organization's code of conduct that includes the POPC's core objectives or substantially similar compliance goals.

- Of the 91 Attestations that were returned, 71 have certified prior to or on December 31, 2016 with the OMIG that they have an effective compliance program that meets the requirements of SSL §363-d and its implementing regulations at 18 NYCRR Part 521.

- Of the 91 Attestations that were returned, 55 have certified that they submitted a DRA certification to OMIG prior to or on December 31, 2016.

Next Steps

9) The OCC will continue to remind those Partners who have not yet returned a completed Attestation and remind them to do so.