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Working Hours and Conditions Post-Graduate Trainees Annual Compliance Assessment Contract Year 8 10/1/08-9/30/09

Executive Summary

With approximately 15,000 of the nation's 100,000 post-graduate trainees working within New York State, considerable attention has focused on monitoring for compliance with the State's work hour requirements. In conjunction with a five-year contract with the New York State Department of Health (DOH), IPRO conducted compliance assessments at all teaching hospitals. A total of 136 compliance visits were conducted in the eighth year of the contract from October 1, 2008 to September 30, 2009, which included annual compliance visits at all 115 teaching facilities in New York State, 5 complaint investigations, and 16 revisits. In total, the working hours of 5,755 residents in the State were reviewed to assess compliance with working hour requirements.

Upon completion of each facility survey, a letter of findings was issued to each facility with a compliance determination. Non-compliance with current requirements was reported to facilities in a statement of deficiencies (SOD). All facilities with documented deficiencies were required to submit a plan for implementing corrective action. All facilities that submit a plan of correction (POC) are assessed for implementation and compliance with their submitted POC at their next visit.

Compliance findings for year eight of the Post-Graduate Trainees Working Hour Compliance Assessment Program include the following:

- Annual compliance reviews were conducted at all 115 teaching facilities, with 107 hospitals found in substantial compliance with requirements and 8 hospitals cited for non-compliance in at least one program area
 - In seven (7) of the facilities cited, only one (1) program area within the facility evidenced non-compliance
 - In one (1) of the facilities cited, two (2) program areas within the facility evidenced non-compliance
- 5 onsite complaint visits investigating 7 program complaints were conducted with a 40% substantiation rate
 - Three (3) of the 5 visits involved three (3) surgical and two (2) anesthesia programs with the complaints not substantiated
 - Two (2) of the 5 visits involved one (1) internal medicine and one (1) OB/GYN program with the complaints substantiated
- In follow-up to identified non-compliance, 16 revisits were conducted to monitor the facility's plan of correction (POC) implementation
 - 94% of revisits evidenced substantial compliance
 - 6% of revisits evidenced at least one element of continued non-compliance

- Of the 20 programs reviewed during the revisits:
 - One (1) of 7 (14%) internal medicine programs evidenced continued non-compliance
 - The eight (8) surgical, three (3) pediatrics, one (1) family practice, and one (1) OB/GYN programs evidenced compliance with their POC
- Six (6) of the 136 (4%) compliance reviews conducted evidenced residents working more than 24 consecutive hours
 - Programs in internal medicine (33.3%), OB/GYN (33.3%), and surgery (33.3%) were equally cited in this area
- Three (3) of the 136 (2%) compliance reviews conducted evidenced residents not receiving one full 24-hour off period each week
 - Programs in family practice (33.3%), internal medicine (33.3%), and surgery (33.3%) were equally cited in this area
- Three (3) of the 136 (2%) compliance reviews conducted evidenced improper separation between working assignments
 - Programs cited were internal medicine (100%)

Annual Compliance Assessment

Exhibits 1 - 2 / Implementation

Exhibit 1 illustrates the 115 annual reviews for the eighth year of the contract conducted between October 2008 and September 2009.

Exhibit 1

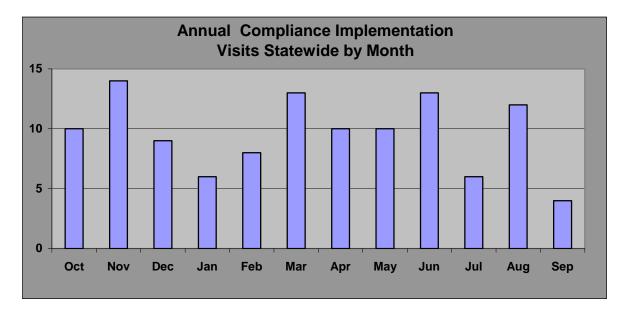
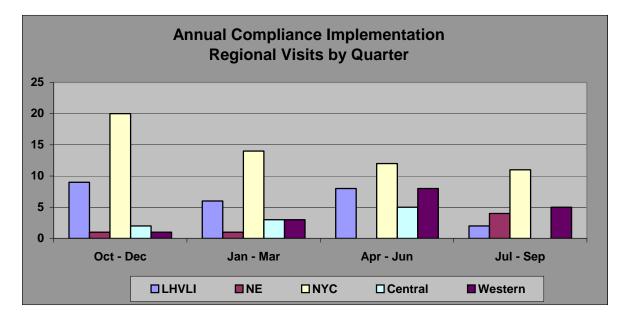


Exhibit 2 illustrates by quarter the distribution of the 115 annual visits by region across the state.

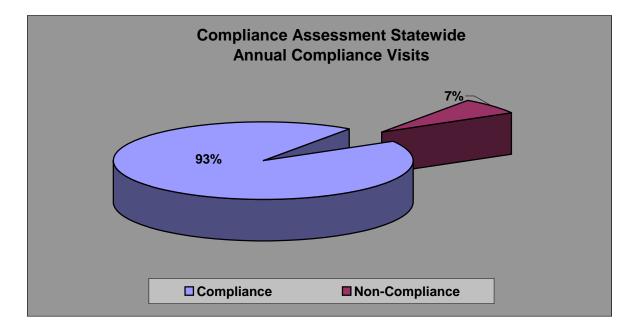


Exhibits 3 – 4 / Compliance Assessment – Statewide and Regional

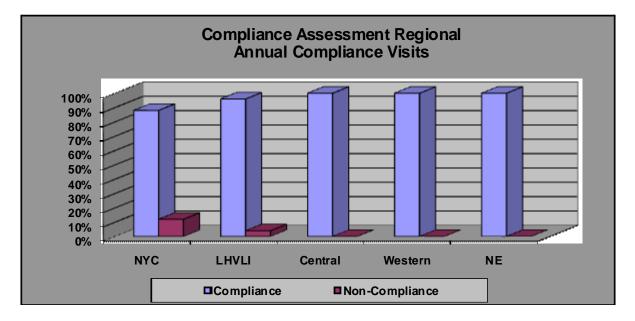
Based on 115 annual compliance visits, 8 (7%) of the facilities evidenced some level of non-compliance at the time of the annual onsite review.

Exhibits 3 and 4 illustrate compliance on a statewide and regional basis respectively. For reporting purposes, non-compliance means that one or more deficiency/finding was identified during the onsite review. Each deficiency/finding cited could result from an issue associated within one or more programs within the facility.

Of the 8 facilities cited for non-compliance, seven (7) evidenced non-compliance in only one program area and one (1) of the facilities cited evidenced non-compliance in two program areas.







Exhibits 5 – 6 / Statewide Compliance – Distribution of Non-Compliance

Concerns continue to be raised regarding the scheduling of onsite visits in July and during the holiday seasons. While it is recognized that throughout the year there are dates and periods of time where routine scheduling for hospitals may be more difficult, due to the large number of surveys to be conducted, compliance surveys were carried out throughout the contract year. All 115 annual compliance surveys were completed between October 2008 and September 2009.

Exhibit 5 illustrates the distribution of the 115 annual visits to the distribution of noncompliance documented for visits completed each month. The information provided reflects a fairly consistent correlation throughout the year between visits conducted and facilities found to be out of compliance with current requirements. Upon review, the data does not appear to indicate that survey outcome was significantly influenced by survey scheduling.



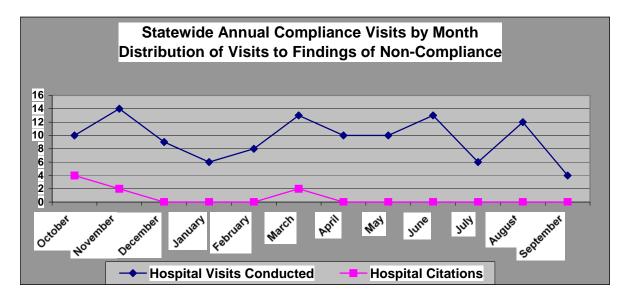


Exhibit 5a illustrates the comparison for contract years 1 - 8 for annual non-compliance for visits completed each month. With the exception of Year 1, which reflects program implementation, the information provided reflects a fairly consistent correlation throughout the years for facilities found to be out of compliance for visits conducted each month of the contract year.

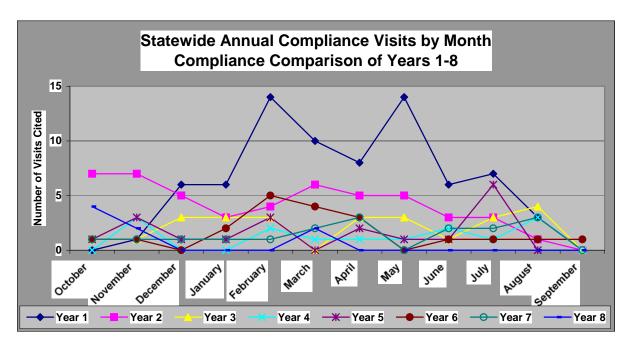


Exhibit 5a

Exhibit 6 presents a detailed assessment of compliance by bed size for the 115 annual visits. Each facility is identified by its bed size, and is evaluated by the percent of non-compliance, as evidenced by the percentage of facility programs that were cited for non-compliance. For example, a facility review that included four teaching programs, surgery, internal medicine, OB/GYN, and pediatrics, and was found out of compliance in only one program, would be out of compliance for 25% of the programs reviewed. For analysis purposes, all sub-specialties were included under the primary program category.

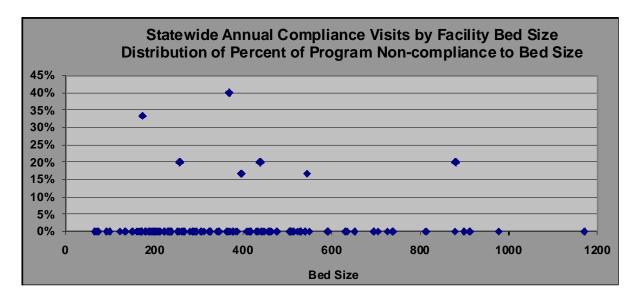


Exhibit 6

None of the annual visits conducted evidenced non-compliance in every teaching program reviewed at that site. In contrast to previous contract year findings, 100% of the annual visits conducted evidenced substantial compliance in at least half of the teaching programs reviewed. The distribution of survey results for the survey period continues to support that non-compliance is not solely related to certified bed size.

Exhibits 7 – 12 / Compliance Assessment – Statewide and Regional Distribution of Findings

New York State requirements limit working hours to an average over four weeks of 80 hours each week. In addition, working assignments are limited to no more than 24 consecutive hours, required non-working periods must follow scheduled assignments and each resident must have one 24-hour off period each week. For the 136 total visits conducted during year eight of the contract, 7% of facilities evidenced some level of non-compliance with requirements.

Exhibits 7-12 demonstrate statewide and regional distribution of findings for the 136 total visits based upon current program requirements. Findings include:

• > 80 Hours Per Week – on average over a four-week period, the workweek is limited to 80 hours per week. In year eight of the contract, none of the visits completed evidenced working hours in excess of 80 hours each week.

• > 24 Consecutive Hours – regulations limit scheduled assignments to no more than 24 consecutive hours. In four percent (4%) of visits conducted, residents were found to be working more than 24 consecutive hours.

• < 24-Hour Off Period – scheduling must include one full 24-hour off period each week. Two percent (2%) of visits conducted evidenced residents not receiving a full 24-hour off period during each week.

• Proper Separation – assigned work periods must be separated by non-working time. Two percent (2%) of visits evidenced working assignments not separated by required non-working time.

• Working Limitations – this category reflects documented inconsistencies in working hour information collected during interview and through observation when compared to a review of documentation. To validate interview data, review staff screen facility documentation not limited to medical records, operating room logs or operative reports, delivery logs, and/or consult logs, to document the date and/or time certain services are provided and recorded. None of the visits conducted evidenced violations in this area.

• QA – each hospital is required to conduct and document ongoing quality assurance/quality improvement (QA/QI) activities for the identification of actual or potential problems in accordance with requirements set forth in statute. No facilities reviewed during year eight were cited for deficiencies in their QA/QI performance. It should be noted that QA/QI would automatically be cited in year eight for any facility that had a repeat deficiency from year seven or in the case of a year eight revisit, a repeat of findings in year eight.

• Governing Body – the responsibility for the conduct and obligations of the hospital including compliance with all Federal, State and local laws, rests with the hospital Governing Body. During year eight of the contract, Governing Body was not cited as an area of non-compliance.

• Working Conditions – working conditions include consideration for sleep/rest accommodations, the availability of ancillary and support services, and the access to and availability of supervising physicians to promote quality supervision. In year eight, no facilities were cited for failing to meet expected working conditions for residents.

• Moonlighting – regulations place responsibility with each hospital to limit and monitor the working hours associated with moonlighting or dual employment situations. Trainees who have worked the maximum number of hours permitted in regulation are prohibited from working outside the facility as physicians providing professional patient care services. No violations pertaining to moonlighting or dual employment requirements were identified in year eight.

• Emergency Department (ED) – for hospitals with more than 15,000 unscheduled emergency department visits, the ED assignments of trainees shall be limited to no more than 12 consecutive hours. For the period of review, no violations were identified for this program area.

• Medical Records – medical record documentation and authentication regulations require that all medical record entries be signed, dated, and timed. No facility visits were found to be substantially non-compliant with medical record entry requirements.

The most notable areas of non-compliance statewide and on a regional basis continues to be working hours in excess of 24 consecutive hours (>24) and residents not receiving a full 24-hour off period during each week (<24).

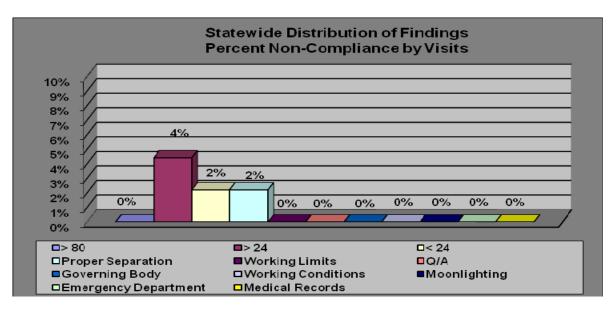
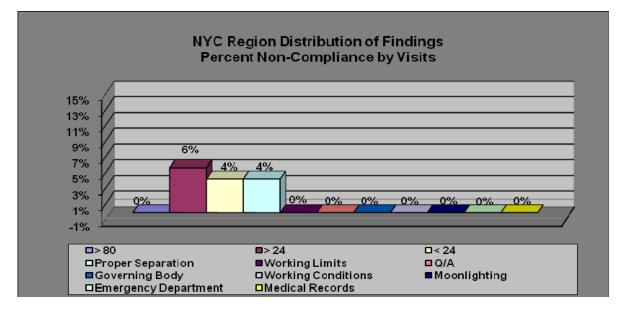


Exhibit 7



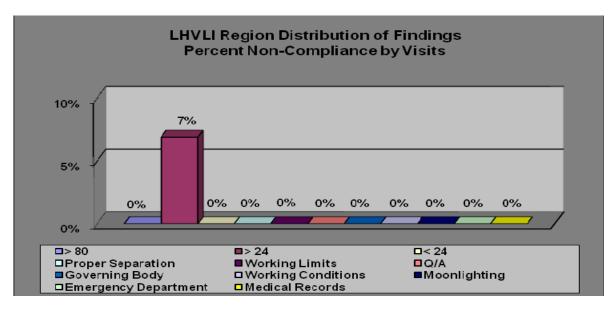
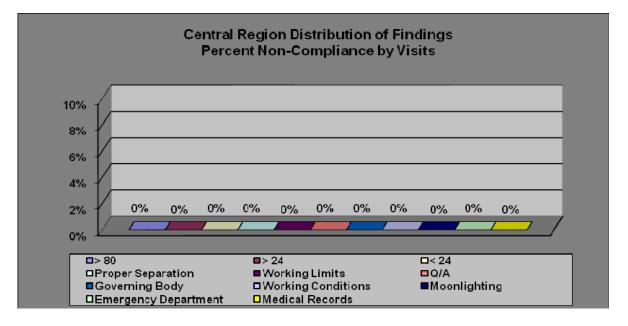


Exhibit 10





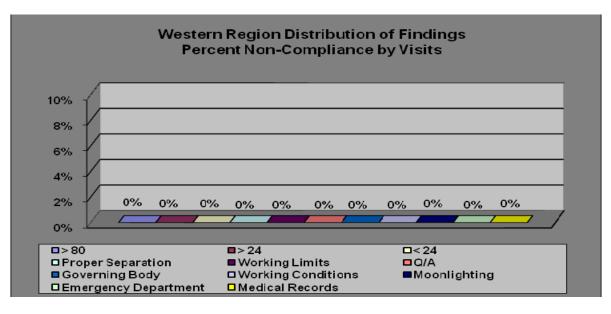
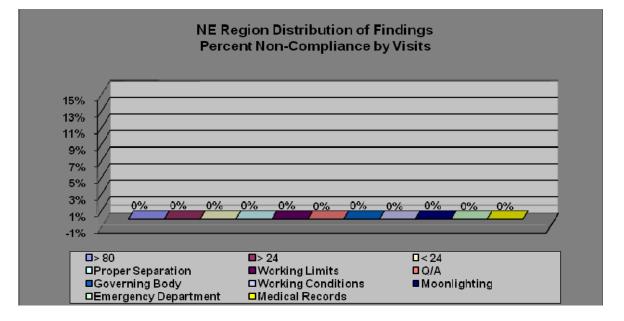


Exhibit 12



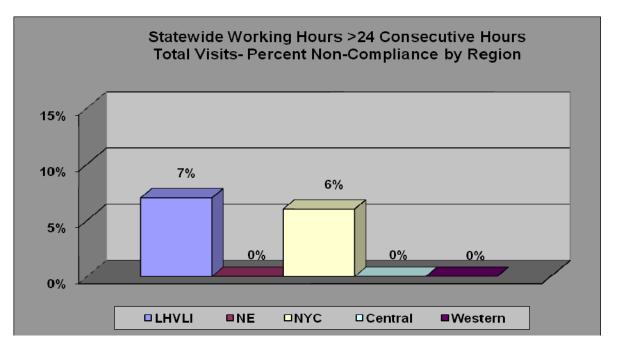
Exhibits 13 – 16 / Compliance Assessment – Working Hours > 24 Consecutive Hours

New York State regulations limit scheduled assignments to no more than 24 consecutive hours. In applying this standard and for determining compliance, an additional unscheduled transition period of up to three hours may be utilized by facilities to provide for the appropriate transfer of patient information.

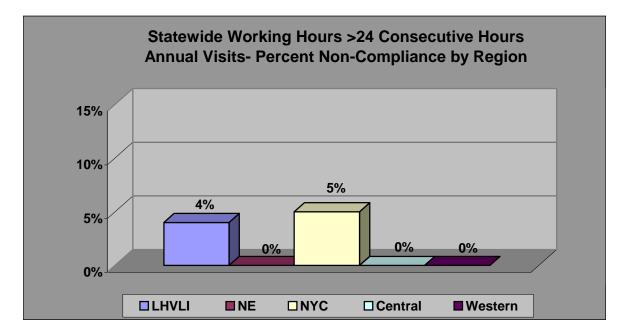
Hospitals have some flexibility in utilizing the three-hour transition period to carry out rounds, grand rounds, and/or the transfer of patient information. New patient care responsibilities may not be assigned during the transition period, and the three-hour period, if used, is counted toward the weekly work hour limit of 80 hours.

For all surveys conducted in year eight of the contract, this area was the most frequently cited area, and for annual visits was equally cited with the required 24-hour off period per week regulation. Statewide, non-compliance was evidenced in 4% of the 136 total surveys conducted and 3% in the 115 annual surveys conducted. Exhibits 13 –16 further illustrate this finding by region, facility bed size, program size, and specialty.

Exhibit 13 – 13a are based on the 136 total visits and 115 annual visits respectively. For surveys conducted at each region's facilities (25 LHVLI, 6 Northeast, 57 New York City, 10 Central, and 17 Western) the non-compliance rate for total visits conducted is consistent with the annual visit findings.







Exhibits 14 and 15 correlate findings to facility bed size and program size (number of residents). The highest percentage of findings for >24 hours was found in facilities with 401-600 beds, followed by facilities with 201- 400 beds for all visits and annual visits. In contrast, the highest percentage of findings for >24 hours was found in facilities with between 101-300 residents at a slightly higher rate than 0-100 residents, and no findings for facilities with 301-500 residents for all visits and annual visits. There were no facilities in year eight with 501+ residents. Exhibits 14 and 15 are based on findings for the 136 total visits conducted. Exhibits 14a and 15a reflect findings for the 115 annual visits.

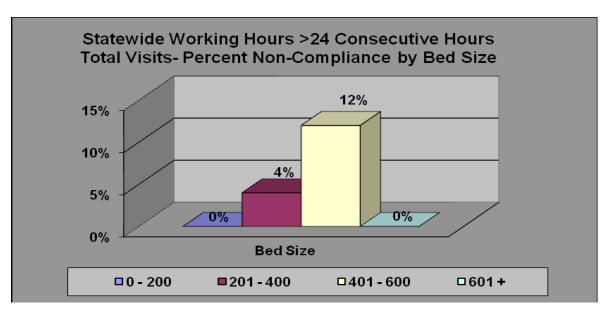


Exhibit 14a

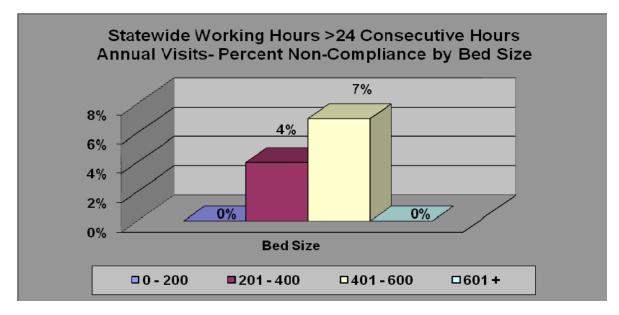


Exhibit 15

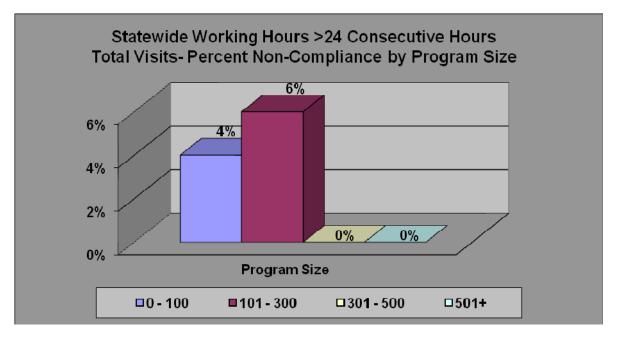
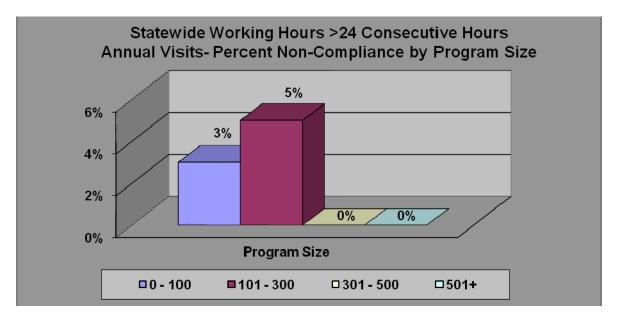
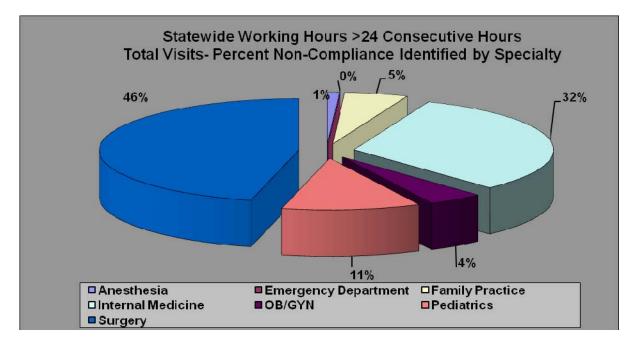


Exhibit 15a



As illustrated in Exhibit 16, based on the 136 total visits conducted and the total residents identified as outliers, 46% of surgery and 32% of internal medicine residents were the most frequently identified, but not necessarily cited, for > 24 consecutive hours. This can, in part, be attributed to the fact that each category includes findings associated with numerous subspecialties and account for 43% of the programs in teaching hospitals throughout the state.



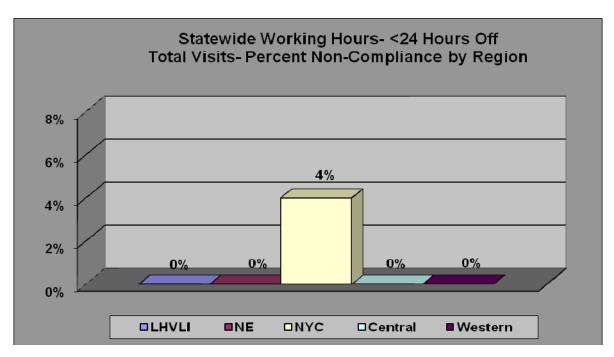
Exhibits 17 – 20 / Compliance Assessment – < 24-Hour Off Period

New York State regulations require that scheduling must include one full 24-hour off period each week free from patient care assignments or responsibilities. Each program determines the schedule week. The majority of programs use a Sunday-to-Saturday schedule; others use a Monday-to-Sunday week. While each may allow for a full weekend off or "Golden Weekend", programs should be mindful that the regulations require a 24-hour off period each week. One difficulty that can present itself with providing a 24-hour off period each week is ensuring that there are 24 hours off post call if this is the only day off for the week.

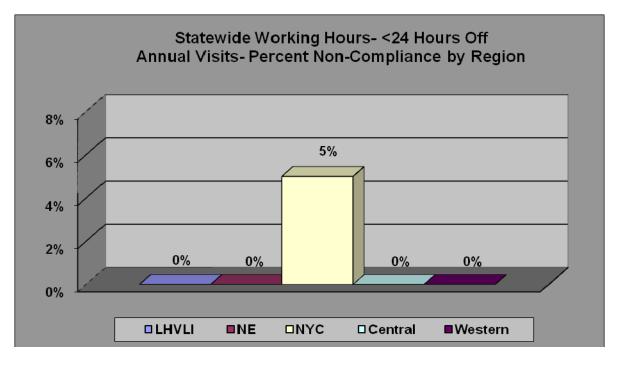
Sick, back-up, and/or jeopardy call, as well as home call systems can also result in noncompliance with the required 24-hour off period per week. Trainees under these call systems need to be available for coverage, and therefore, are not free from all patient care responsibilities even if they are not called back into the facility. If a trainee is scheduled for multiple consecutive days of call (i.e., back-up call every day for one month), the trainee would not have the required 24-hour off period per week.

For all surveys conducted in year eight of the contract, this area was the second most frequently cited and was equally cited with the >24 consecutive hours regulation for annual surveys. Statewide, non-compliance was evidenced in 2% of the 136 total surveys conducted and 3% in the 115 annual surveys conducted. Exhibits 17 – 20 further illustrate this finding by region, facility bed size, program size, and specialty.

Exhibits 17 – 17a are based on the 136 total visits and 115 annual visits respectively. For surveys conducted at each region's facilities (25 LHVLI, 6 Northeast, 57 New York City, 10 Central, and 17 Western) the non-compliance rate for total visits conducted is consistent with the annual visit findings.







Exhibits 18 and 19 correlate findings to facility bed size and program size (number of residents) in a facility program. The highest percentage of findings for <24 hours off was found equally in facilities with 0-200 beds and 601+ beds, followed closely by facilities with 201-400 beds for all visits. The highest percentage of findings for annual visits for <24 hours off was found highest in facilities with 601+ beds, followed closely by facilities with 0-200 beds, and 201-400 beds. The percentage for 0-200 beds and 201-400 beds was identical for all visits and annual visits. In contrast, the highest percentage of findings for <24 hours off was found in facilities with between 0-100 residents in the facility teaching program, followed by facilities with between 101-300 residents, and no findings were found in facilities with 501+ residents during year eight. Exhibits 18 and 19 are based on findings for the 136 total visits conducted. Exhibits 18a and 19a reflect findings for the 115 annual visits.

Exhibit 18

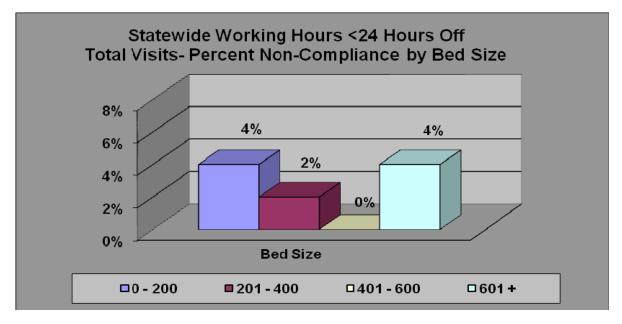
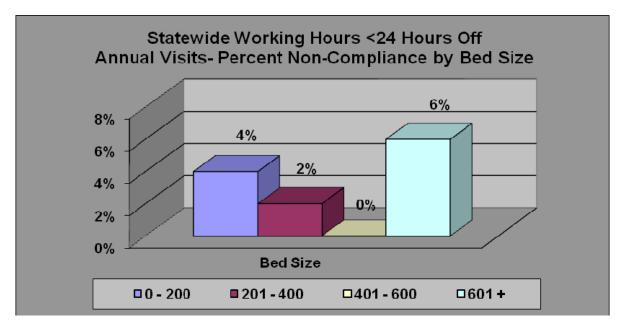


Exhibit 18a



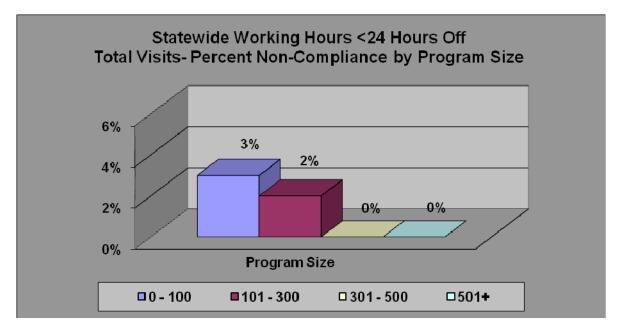
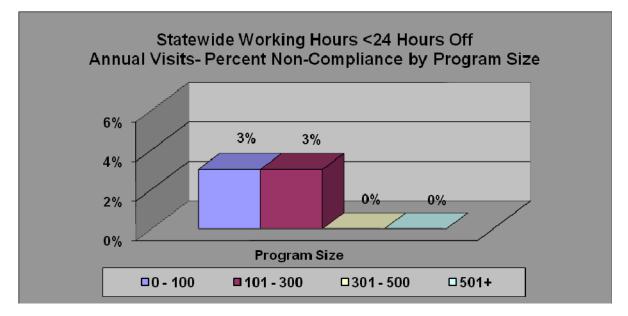


Exhibit 19a



As illustrated in Exhibit 20, based on the 136 total visits conducted and the total residents identified as outliers, 45% of surgery and 26% of internal medicine residents were the most frequently identified, but not necessarily cited, for <24 hours off. This also can, in part, be attributed to the fact that each category includes findings associated with numerous subspecialties and account for 43% of the programs in teaching hospitals throughout the state.

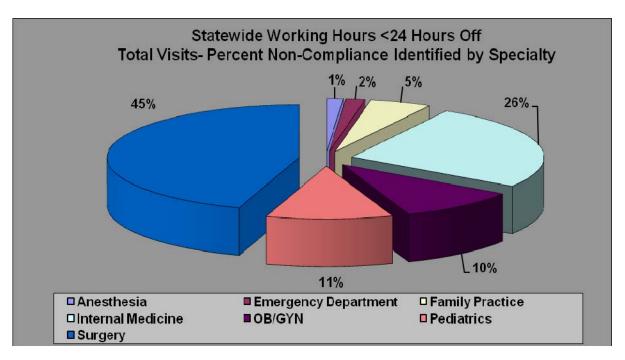


Exhibit 20

Exhibits 21 – 22 / Compliance Assessment – Statewide for Complaint Visits and Revisits

In accordance with program requirements, IPRO also evaluated and investigated complaints received by the DOH specific to resident working hours. In total, for year eight of the contract, the DOH received 5 facility working hour complaints involving 7 programs. Exhibit 21 indicates that 40% of the complaints were substantiated following investigation. Three (3) of the 5 complaints related to 3 surgical programs and 2 anesthesia programs with none of these complaints substantiated. Two (2) of the 5 complaints related to 1 internal medicine and 1 OB/GYN program and were substantiated.

Exhibit 21



Revisits, focused reviews of previously identified issues, were conducted for all facilities issued a statement of deficiency to monitor the plan of correction implementation. In comparison to 7% non-compliance findings at annual compliance visits, at revisit 6% of facilities continued to evidence at least one element of non-compliance (Exhibit 22) at the time of the revisit.

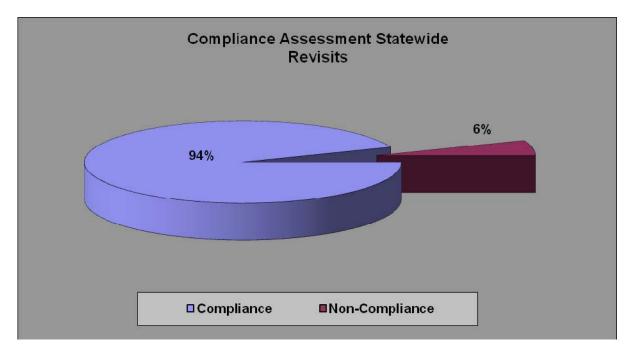
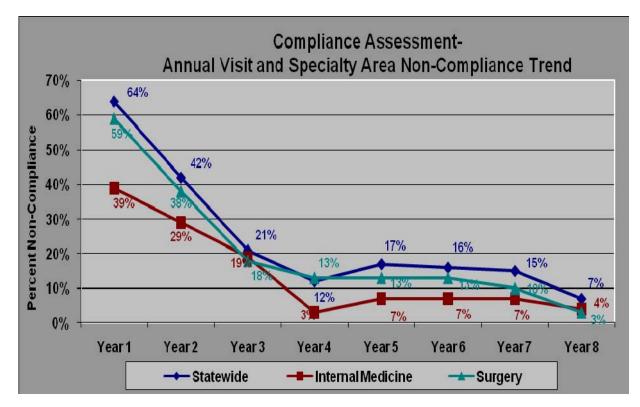


Exhibit 23 / Compliance Assessment – Annual Visit and Program Area Compliance Trend

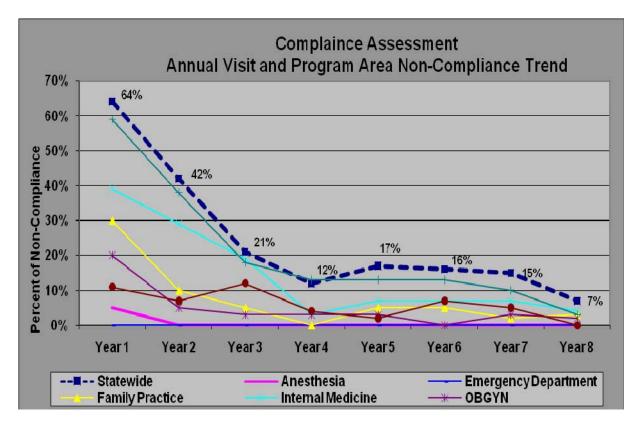
Throughout the eight years of the contract, IPRO has tracked specialty areas by specific citations. Two specialty areas, internal medicine and surgery, were identified as the specialty areas most frequently cited for non-compliance with the regulations.

Exhibit 23 demonstrates that as total annual visit compliance among facilities has improved statewide throughout the eight years, compliance in these two specialty areas has improved at nearly the same rate. Compliance statewide and among these two specialty areas improved dramatically in year one through four and has stayed fairly consistent in year five through eight.

Exhibit 23a demonstrates annual visit compliance trends for all program areas statewide for the eight years.







Program Strengths

During the eight years of IPRO's contract we have looked at changes facilities have made in response to the duty hours. This year we collected 115 such changes based upon discussion with Program Directors, program coordinators and/ or chief residents.

These changes can be grouped into 5 categories: schedule changes, staffing changes, new software, education/ procedural changes and other. The following highlights summarize each category:

- 1. Schedule Changes
 - Changed hours of night float earlier or later and increased numbers of days for night float
 - Changed hours of morning report and/ or allowed post call residents to present cases first
 - Changed number of calls per week or month
 - Increased or decreased upper levels using home call
 - Changed hours for pre call day
- 2. Staffing Changes
 - Hospitalists to cover patients at night or free up residents during the day
 - Nurse practitioners and Physicians Assistants for coverage
 - Fellows on research to cover call
 - More use of attendings for weekend days
 - Increased number of residents used in call schedule
 - Use of a day admitting team
 - Chief call changed to a back up system to allow more inhouse patient care during busy hours and / or OR time
 - Use of inhouse moonlighting to lessen call
 - Eliminated overnight call for certain levels and increased daily hours
 - Team approach for coverage
 - Buddy call, mainly in Radiology: Buddy call consists of a junior resident working on-call with a senior resident to ensure competence with reading films, scans, and performing radiology on-call duties
- 3. Education/ Procedural Changes
 - Protected education time
 - Changed clinic times
 - Increased and /or decreased rotations to facilitate education
 - Added new research opportunities
 - Added new clinical programs
 - Added new attendings who changed education focus
 - More consistent journal club and rounds
 - Conferences available on line
 - More focused monthly lectures i.e.: 1 topic for whole month
 - Program Director changes to facilitate educational focus

- More theme based patient care with web based modules
- More Board prep
- More online simulation
- Cultural competency conferences
- 4. Software Changes
 - Software for duty hour monitoring
 - Software for handoffs
 - Software for simulation
 - Software for didactic education
 - More Web based education
 - Case monitoring
- 5. Other
 - Use of binders to maintain all required survey information

Program Process Continual Improvements

- IPRO will continue to identify other studies, which when complete, can assist facilities with focus areas to accomplish the greatest impact on compliance. One such study is by the Institute of Medicine (IOM), "Optimizing Graduate Medical Trainee Hours and Work Schedules to Improve Patient Safety"
- Review staff will continue to update facility contact information during the entrance conference and IPRO will continue to keep an updated listing of facility CEO and residency program contacts
- IPRO will continue to review schedules, as requested by facilities, to assist in achieving compliance
- IPRO will continue to monitor survey processes, such as unannounced visits, staggered survey schedule, and site review protocols, as well as tracking and trending of program strengths, survey findings, feedback, and other QA/QI measures.

Summary of Exhibits

| Exhibit 1 | Implementation – Annual Compliance Visits Statewide by Month |
|-------------|---|
| Exhibit 2 | Implementation – Annual Compliance Visits Regional by Quarter |
| Exhibit 3 | Compliance Assessment – Statewide / Annual Compliance Visits |
| Exhibit 4 | Compliance Assessment – Regional / Annual Compliance Visits |
| Exhibit 5 | Statewide Annual Visit Compliance – Distribution of Visits to Findings of Non-Compliance |
| Exhibit 5a | Statewide Annual Visit Compliance – Visits by Month Compliance Comparison Years 1-8 |
| Exhibit 6 | Statewide Annual Visit Compliance – Distribution of Non-Compliance to Bed Size |
| Exhibit 7 | Statewide – Distribution of Findings / Total Visits |
| Exhibit 8 | New York City Region – Distribution of Findings / Total Visits |
| Exhibit 9 | Lower Hudson Valley & Long Island Region – Distribution of Findings / Total Visits |
| Exhibit 10 | Central Region – Distribution of Findings / Total Visits |
| Exhibit 11 | Western Region – Distribution of Findings / Total Visits |
| Exhibit 12 | Northeast Region – Distribution of Findings / Total Visits |
| Exhibit 13 | Statewide - > 24 Hours by Region / Total Visits |
| Exhibit 13a | Statewide - > 24 Hours by Region / Annual Visits |
| Exhibit 14 | Statewide - > 24 Hours by Facility Bed Size / Total Visits |
| Exhibit 14a | Statewide - > 24 Hours by Facility Bed Size / Annual Visits |
| Exhibit 15 | Statewide - > 24 Hours by Program Size / Total Visits |
| Exhibit 15a | Statewide - > 24 Hours by Program Size / Annual Visits |
| Exhibit 16 | Statewide - > 24 Hours by Specialty / Total Visits |
| Exhibit 17 | Statewide - < 24 Hours Off by Region / Total Visits |
| Exhibit 17a | Statewide - < 24 Hours Off by Region / Annual Visits |
| Exhibit 18 | Statewide - < 24 Hours Off by Facility Bed Size / Total Visits |

| Exhibit 18a | Statewide - < 24 Hours Off by Facility Bed Size / Annual Visits |
|-------------|--|
| Exhibit 19 | Statewide - < 24 Hours Off by Program Size / Total Visits |
| Exhibit 19a | Statewide - < 24 Hours Off by Program Size / Annual Visits |
| Exhibit 20 | Statewide - < 24 Hours Off by Specialty / Total Visits |
| Exhibit 21 | Compliance Assessment – Work Hour Complaint Visits |
| Exhibit 22 | Compliance Assessment – Hospital Revisits |
| Exhibit 23 | Compliance Assessment – Annual Visit and Specialty Area Non-Compliance Trend |
| Exhibit 23a | Compliance Assessment – Annual Visit and Program Area Non-Compliance Trend |

Appendices

Appendix A contains the following comparison exhibits based on total visits conducted at facilities in Years one through eight:

| Exhibit 24 | Years 1- 8 Comparisons Assessment - Annual Compliance Visits Statewide by Month |
|------------|---|
| Exhibit 25 | Years 1- 8 Comparisons Compliance Assessment- Statewide Annual Compliance Visits |
| Exhibit 26 | Years 1- 8 Comparisons Compliance Assessment- Regional Annual Compliance Visits |
| Exhibit 27 | Years 1-8 Comparisons Compliance Assessment- Statewide Distribution of Findings |
| Exhibit 28 | Years 1- 8 Comparisons Compliance Assessment- New York City Region Distribution of Findings |
| Exhibit 29 | Years 1- 8 Comparisons Compliance Assessment- Lower Hudson Valley & Long Island Region Distribution of Findings |
| Exhibit 30 | Years 1- 8 Comparisons Compliance Assessment- Central Region Distribution of Findings |
| Exhibit 31 | Years 1- 8 Comparisons Compliance Assessment- Western Region Distribution of Findings |
| Exhibit 32 | Years 1- 8 Comparisons Compliance Assessment- Northeast Region Distribution of Findings |
| Exhibit 33 | Years 1-8 Comparisons Compliance Assessment- Statewide >24 by Region |
| Exhibit 34 | Years 1- 8 Comparisons Compliance Assessment- Statewide >24 by Facility Bed Size |
| Exhibit 35 | Years 1- 8 Comparisons Compliance Assessment- Statewide >24 by Program Size |
| Exhibit 36 | Years 1- 8 Comparisons Compliance Assessment- Statewide >24 by Specialty |
| Exhibit 37 | Years 1-8 Comparisons Compliance Assessment- Statewide <24 by Region |
| Exhibit 38 | Years 1- 8 Comparisons Compliance Assessment- Statewide <24 by Facility Bed Size |
| Exhibit 39 | Years 1- 8 Comparisons Compliance Assessment- Statewide <24 by Program Size |

Exhibit 40 Years 1-8 Comparisons Compliance Assessment- Statewide <24 by Specialty
Exhibit 41 Years 1-8 Comparisons Compliance Assessment- Statewide Complaint Visits
Exhibit 42 Years 1-8 Comparisons Compliance Assessment- Statewide Revisits
Exhibit 43 Years 1-8 Comparisons Compliance Assessment- Statewide >24 and <24 Non-Compliance Comparison
Exhibit 44 Years 1-8 Comparisons Compliance Assessment- Statewide >24 and <24 Non-Compliance Deparison

* Data reported reflects a compilation of information and data collected through routine surveillance activities. The information is based upon a sample of post-graduate trainees in New York State.