

Working Hours and Conditions Post-Graduate Trainees Annual Compliance Assessment Contract Year 3 10/1/03-9/30/04

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 three-year contract with the DOH, IPRO conducted compliance assessments at all teaching hospitals. A total of 158 compliance visits were conducted in the third year of the contract from October 1, 2003 to September 30, 2004, which included annual compliance visits at all 118 teaching facilities in New York State, 10 complaint investigations, and 30 re-visits. In total, the working hours of more than 8,221 residents in the State were reviewed to assess compliance with working hour requirements.

Upon completion of each on-site 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 scheduled visit.

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

- Annual compliance reviews were conducted at all 118 teaching facilities, with 93 hospitals found in substantial compliance with requirements and 25 hospitals cited for non-compliance in at least one program area
 - In 11 of the facilities cited, only one (1) program area within the facility evidenced non-compliance
 - In 11 of the facilities cited, two (2) program areas within the facility evidenced non-compliance
 - In three (3) of the facilities cited, three or more program areas within the facility evidenced non-compliance
 - 10 on-site complaint investigations were conducted with a 30% substantiation rate
 - Five (5) of the 10 complaints related to surgical programs with three (3) complaints substantiated
 - Four (4) of the 10 complaints related to internal medicine programs with no complaints substantiated
 - One (1) of the 10 complaints related to ob/gyn program with the complaint not substantiated

- In follow-up to identified non-compliance, 30 re-visits were conducted to monitor the facility's plan of correction (POC) implementation
 - 70% of re-visits evidenced substantial compliance
 - 30% of re-visits evidenced at least one element of continued non-compliance
 - 25 re-visits focused on surgical compliance issues with 28% continued non-compliance
- 24 of the 158 (15%) compliance reviews conducted evidenced residents working more than 24 consecutive hours
 - Programs in internal medicine (39%), surgery (33%), and pediatrics (14%) were most frequently cited in this area
- 7 of the 158 (4%) compliance reviews conducted evidenced improper separation between working assignments
 - Programs in internal medicine (63%) and surgery (37%) were most frequently cited
- 4 of the 158 (3%) compliance reviews conducted evidenced residents not receiving one full 24-hour off period each week
 - Programs in surgery (75%) and pediatrics (25%) were most frequently cited
- None of the 158 compliance reviews conducted evidenced residents working more than 80 hours averaged over four weeks

Annual Compliance Assessment

Exhibits 1 - 2 / Implementation

Exhibit 1 shows all 118 annual reviews for the third year of the contract conducted between October 2003 and August 2004.

Exhibit 1

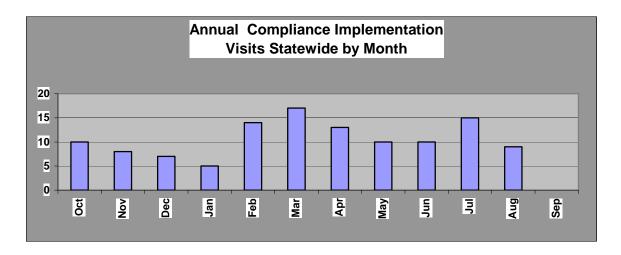
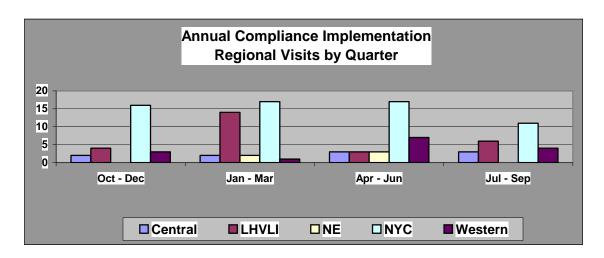


Exhibit 2 illustrates by quarter how the 118 annual visits were distributed by region across the State.

Exhibit 2



Exhibits 3 – 4 / Compliance Assessment- Statewide and Regional

Based on 118 annual compliance visits, 25 (21%) of the facilities evidenced some level of non-compliance at the time of the annual on-site review.

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

Of the 25 facilities cited for non-compliance, 11 evidenced non-compliance in only one program area, 11 of the facilities cited evidenced non-compliance in two program areas, and three (3) facilities evidenced non-compliance in three or more program areas.

Exhibit 3

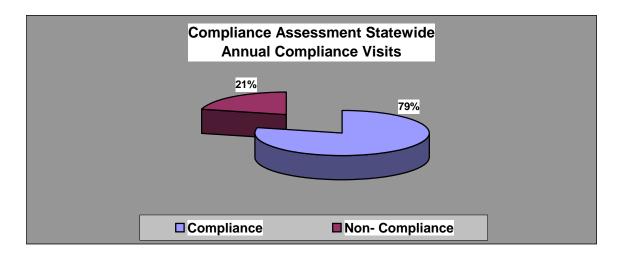
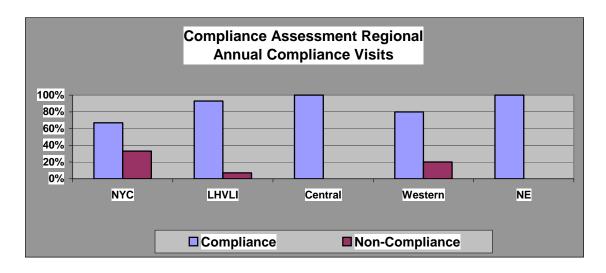


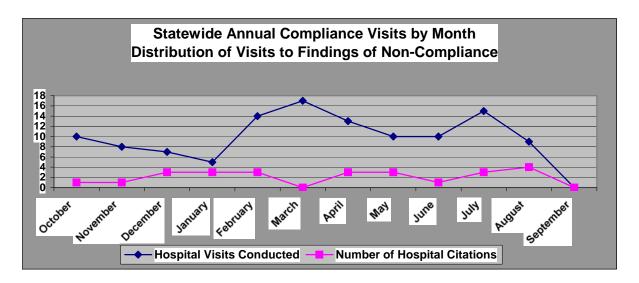
Exhibit 4



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

Concerns continue to be raised regarding the scheduling of on-site 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 118 annual compliance surveys were completed between October 2003 and August 2004. No annual surveys were conducted in September 2004, the close of the contract year. Exhibit 5 illustrates the distribution of the 118 annual visits to the distribution of non-compliance 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 the time period the survey was conducted had a significant impact on whether a facility was found in compliance. In July, for example, the distribution of surveys conducted to findings of non-compliance does not indicate that survey outcome was significantly influenced by survey scheduling.

Exhibit 5



To further support the concern regarding surveys at the start of the resident year (July) and newness of PGY 1's, we conducted a PGY study comparing the time during the beginning of residency training (July- September, extended to December to obtain sample) and the end of the resident training year (March- May, excluding June due to graduations, vacations, etc.). The study used the annual visits that were cited for >24 consecutive hours. While the PGY 1's tend to show the highest percentage of outliers, a systemic issue can affect all PGY levels tending toward non-compliance. Within the limitations of this study, the analysis does not support that PGY 1's in the beginning months of residency training are the sole cause or highest level of >24 consecutive hours, as illustrated in Table 1. The percent outliers includes those residents that were >24 + 3 hours transition time out of the total residents >24 consecutive hours.

Table 1: Comparison of findings of periods of residency training year in succession.

Findings	Month of Residency		
	9-11 (1)	1,2,4-6	9-11 (2)
# residents in sample	998	451	635
% residents >24 hours			
PGY 1	23%	16%	27%
PGY 2	18%	13%	9%
PGY 3	10%	4%	8%
PGY 4	6%	7%	11%
PGY 5	6%	4%	3%
Total	15%	9%	12%
% outliers >24 hours			
PGY 1	41%	29%	48%
PGY 2	33%	32%	25%
PGY 3	23%	9%	29%
PGY 4	23%	27%	32%
PGY 5	36%	36%	19%
Total	34%	27%	35%

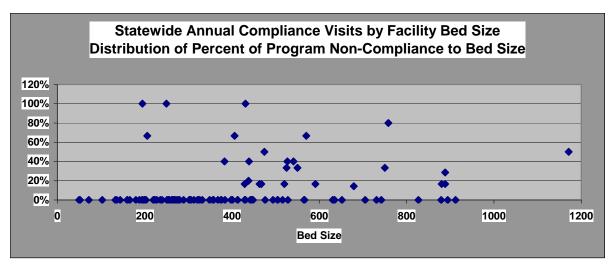
Months 9 – 11 (1): March, April, May 2003

Months 1,2,4-6: July, August, October-December 2003

Months 9 – 11 (2): March, April, May 2004

Exhibit 6 presents a detailed assessment of compliance by bed size for the 118 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



Three percent (3%) of the annual visits conducted evidenced some level of non-compliance in every teaching program reviewed at that site. In contrast, 95% 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 supports 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 hospitals surveyed during year three of the contract, 21% of facilities evidenced some level of non-compliance with requirements.

Exhibits 7-12 demonstrate statewide and regional distribution of findings for the 158 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 three 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 15% 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. Three percent (3%) of visits conducted reported residents not receiving a full 24-hour off period during each week.
- Proper Separation assigned work periods must be separated by non-working time. Four percent (4 %) of visits reported 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 and/or operating room logs or operative reports, delivery logs, consult logs, to document the date and/or time certain services are provided and recorded. Four percent (4%) of 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. Four percent (4%) of facilities reviewed during year three were cited for deficiencies in their QA/QI performance. It should be noted that QA/QI would automatically be cited in year three for any facility that had a repeat deficiency from year two or in the case of a year three re-visit, a repeat of findings in year three.
- 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 three of the contract, Governing Body was cited once 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 three, 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 three.
- 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.

The most notable area of non-compliance statewide and on a regional basis continues to be working hours in excess of 24 consecutive hours (>24).

Exhibit 7

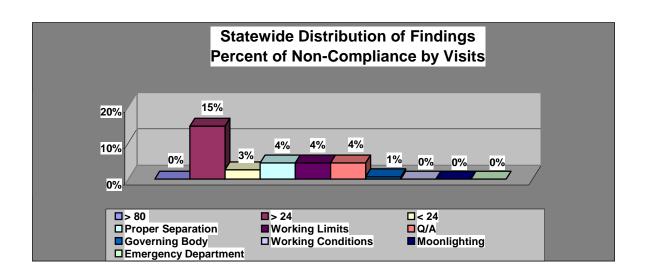


Exhibit 8

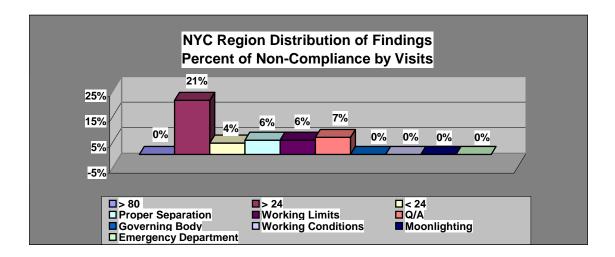


Exhibit 9

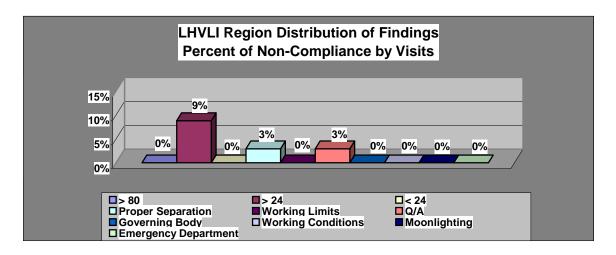


Exhibit 10

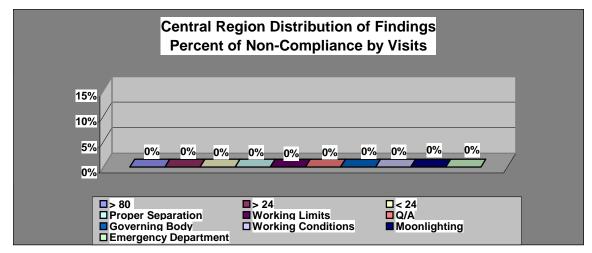


Exhibit 11

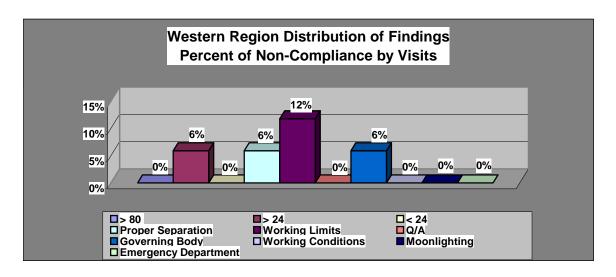
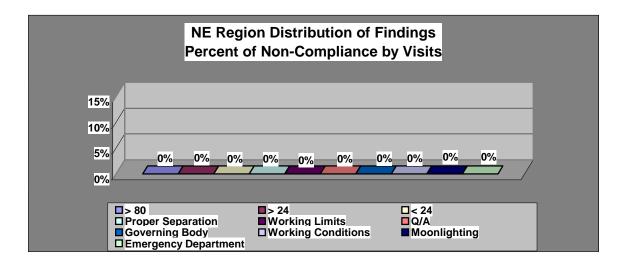


Exhibit 12



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 three of the contract, this area was the most frequently cited. Statewide, non-compliance was evidenced in 15% of the surveys conducted. Exhibits 13 –16 further illustrate this finding by region, facility bed size, program size, and specialty. Exhibit 13 – Based upon the 158 total visits performed, 21% of facilities in the New York City region were found to be out of compliance with this work hour regulation. The findings for the remaining regions are LHVLI at 9%, Western at 6%, and Northeast and Central at 0%.

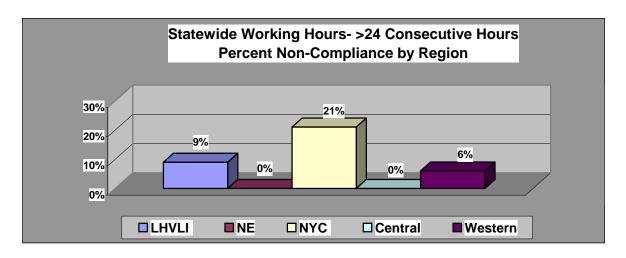
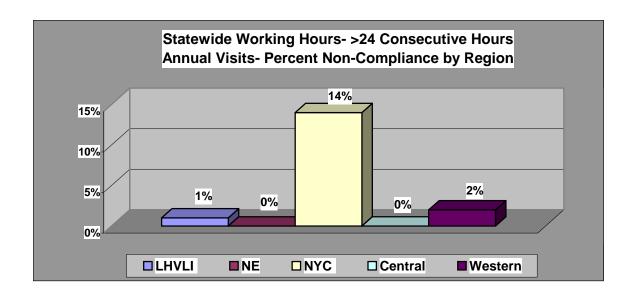


Exhibit 13

Exhibit 13a – In comparison, this exhibit is based upon the 118 annual visits performed. During the annual visit, New York City had 14% of facilities out of compliance with this work hour regulation. The findings for the remaining regions are Western at 2%, LHVLI at 1%, and Northeast and Central at 0%.

Exhibit13a



Exhibits 14 & 15 correlate findings to facility bed size and program size (number of residents) in a facility teaching program. While facilities with more than 600 beds were cited most frequently, the highest percentage of findings for >24 hours was found in facilities with between 301-500 residents in the facility teaching program for all visits and equal at 100% for annual visits. Exhibits 14 & 15 are based on findings for the 158 total visits conducted. Exhibits 14a & 15a reflect findings for the 118 annual visits.

Exhibit 14

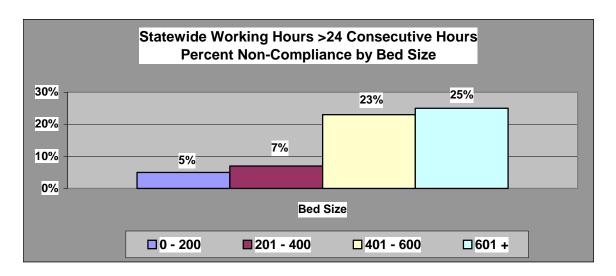


Exhibit 14a

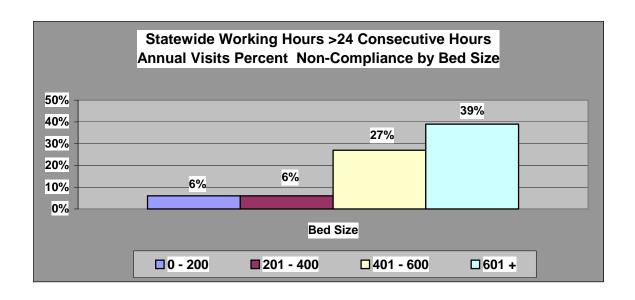


Exhibit 15

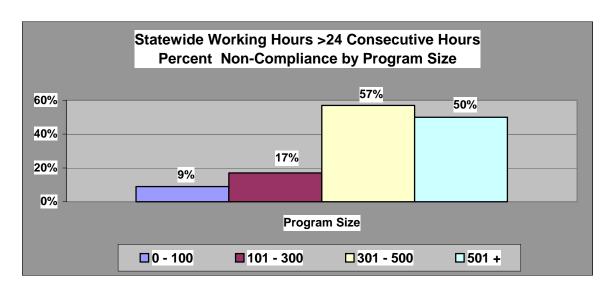
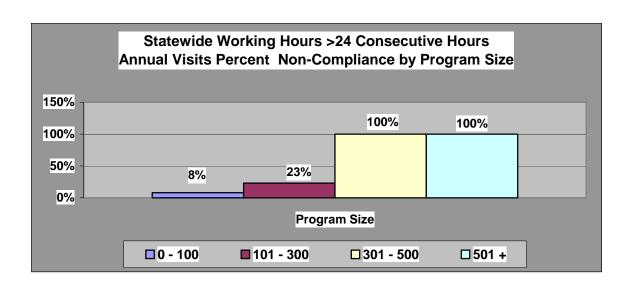
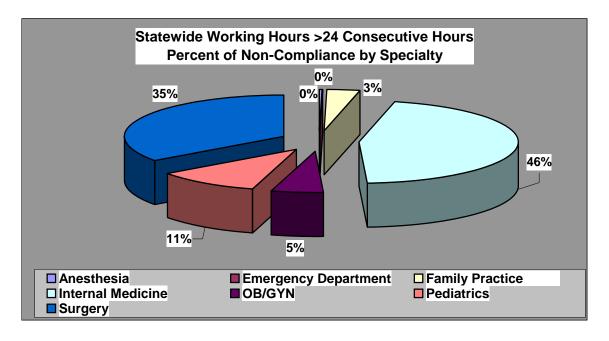


Exhibit 15a



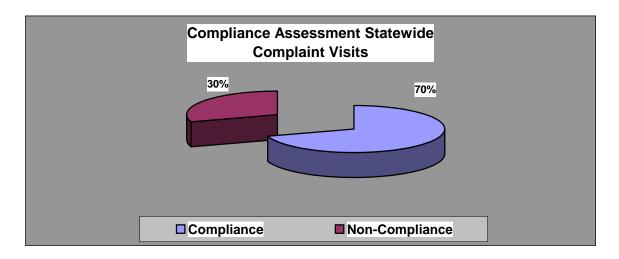
As illustrated in Exhibit 16, based upon the 158 total visits conducted, surgery at 35 % and internal medicine at 46% were the most frequently cited specialty areas for > 24 hours. This can, in part, be attributed to the fact that each category includes findings associated with numerous subspecialties and account for 44% of the programs in teaching hospitals throughout the state.

Exhibit 16



In accordance with program requirements, IPRO also evaluated and investigated complaints received by the DOH specific to resident working hours. In total, for year three of the contract, the DOH received 10 working hour complaints. Exhibit 17 indicates that 30% of complaints were substantiated following investigation. Five (5) of the 10 complaints related to surgical programs with three (3) of these complaints substantiated. Four (4) of the 10 complaints were specific to internal medicine programs and none of these were substantiated. One (1) complaint related to the ob/gyn program and this was not substantiated.

Exhibit 17



Revisits, focused reviews of previously identified issues, were conducted for a sample of facilities to monitor a facility's Plan of Correction implementation. In comparison to 21% non-compliance findings at annual compliance visits, at revisit, 70% of facilities were found in substantial compliance and 30% of facilities continued to evidence at least one element of non-compliance (Exhibit 18) at the time of the re-visit.

Exhibit 18

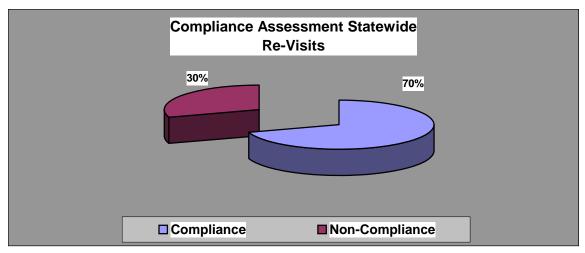
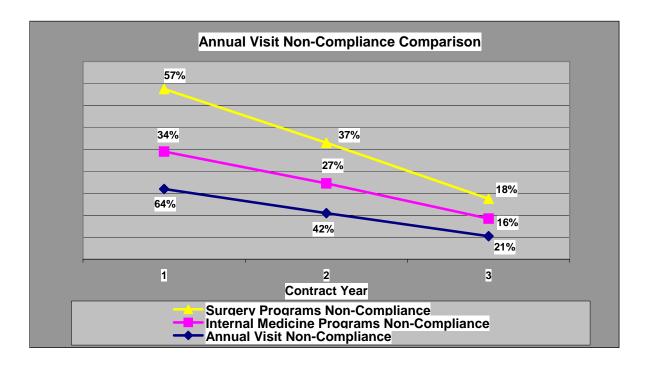


Exhibit 19 / Compliance Assessment – Annual and Specialty Area Compliance Trend

Throughout the three years of the contract, two specialty areas, internal medicine and surgery, were identified as the specialty areas most frequently cited for non-compliance with the regulations. IPRO has tracked these two specialty areas by specific citations for the entire three years. Exhibit 19 demonstrates that as total annual visit compliance among facilities has improved, compliance in these two specialty areas has improved at nearly the same rate.

Exhibit 19



Strategies for Improvement

In conjunction with review activities, efforts focused on identifying program strengths or strategies for improvement. The following program enhancements merit consideration and may, if appropriately implemented, assist facilities in the development of system improvements. Any improvement, however, should be carefully considered and evaluated to ensure that it meets facility needs and has the desired impact.

- IPRO has provided more educational sessions and observed an increase in education provided by facilities for new PGY 1 level trainees in the month of June. Attention to enforcing and monitoring compliance among first year residents has significantly impacted overall compliance levels.
- Facilities should continue to review and amend policies, as appropriate, to ensure consistency with current regulations and to accurately reflect current facility practices. Review findings have demonstrated that, in some instances, facility policies misrepresent requirements and/or outline a hospital policy that is not fully consistent with State requirements. In addition, it should be noted that while facilities may set forth policies that are more stringent/restrictive than State requirements, careful attention must be given to ensuring that such policies reflect actual practice. Each facility is responsible for meeting official requirements, and, similarly accountable for adhering to its own established policies.
- The distribution of assignments and patient care responsibilities among teams of residents can provide an opportunity to distribute workload, promote continuity of patient care, and encourage group/team initiatives.
- Alternative scheduling options should be considered in developing work hour policies and in responding to identified problems. Any scheduling pattern, however, should be carefully considered to ensure that it meets facility needs. Scheduling options can be part of an appropriate solution. If, however, the merits of such initiatives are not fully considered, the impact of implementation may actually create other problem areas.
- Increased attention to compliance with the 24 consecutive hour work rule could directly impact facility compliance. Findings for three full years of compliance reviews indicate that the area most frequently cited is working hours in excess of 24 consecutive hours. This finding is in contrast to previous surveillance findings that identified the most frequent area of noncompliance as working greater than 80 hours during a work week. This would appear to demonstrate that facilities have taken steps to reduce total working hours, thus improving compliance with the 80-hour work week requirement. In practice, therefore, greater attention to limiting scheduled assignments to 24 consecutive hours and reinforcing the need for trainees to complete assignments/transition patient care responsibilities, could notably improve overall compliance.
- Ongoing assessment of facility staffing levels, access to support services and ancillary personnel are key factors in assuring compliance. Work load assessments specific to areas such as phlebotomy, IV therapy, etc., to identify peak periods of need, may assist facilities in

deploying resources more efficiently. Where feasible the hiring and assignment of professional support staff may significantly improve a facility's ability to respond to resident work hour issues.

Future Opportunities

The program to conduct the focused review of working hours in teaching hospitals across New York State is supported by legislation and program funding. The third contract year was completed September 30, 2004. During the six month extension period:

- DOH and IPRO staff will continue to work with the provider community to clarify program requirements and assist facilities in the development and implementation of strategies for ensuring compliance.
- Continued attention in the review process will be given to ensuring that previously identified problems have been corrected. Data will be collected to evaluate facility QA/QI initiatives and assess the effectiveness of such measures. Review activities will recognize facilities that have exhibited a commitment to ensuring compliance. In addition, attention will focus on the obligations of each hospital's Governing Body to assure compliance and to address previously identified problems.
- Facilities that evidence repeat non-compliance will be closely monitored to ensure that each facility's plan of correction is fully implemented. The effectiveness of facility QA/QI initiatives will be documented.
- Efforts will continue to focus on identifying facility processes that improve compliance levels, while continuing to meet accreditation requirements. State requirements will be evaluated in the context of other national or accreditation requirements to identify potential areas of inconsistency or concern. Information will be shared with all hospitals to assist in identifying and evaluating the impact of all applicable requirements.
- A staggered survey schedule, carried out throughout the extension period, will be used to ensure that scheduling alone does not impact compliance findings.
- Review staff will continue to evaluate the effectiveness of the unannounced visit by documenting actions taken during the first several hours of the survey. To facilitate the survey process, entrance and exit conferences will remain optional meetings to reduce concerns raised by facilities that surveys are disruptive to facility operations and that convening key hospital personnel on short notice is difficult. It is recognized that the process of assembling an impromptu group of key personnel to attend the entrance and/or exit conferences, can be inconvenient and may be unnecessary to expedite the survey process. Upon entering a facility, IPRO review staff will contact the designated facility representative and/or alternate, conduct a brief and informal entrance conference, and request assistance in facilitating the review team's access to patient care areas and in scheduling interviews. A more formal entrance and exit conference is not necessary, but can be scheduled at the request of the facility. Survey findings

are only released to facilities by the DOH upon receipt/review of the documentation submitted to the DOH by IPRO.

- Alternative on-site review protocols will continue to be developed and implemented to promote the accuracy and legitimacy of survey findings. Compliance findings will continue to be based upon a wide range of review activities. Observation, interview and the detailed review of policies/procedures, internal review activities, medical records, operative reports/logs, and other records/documents, currently serve as the basis of all review findings.
- IPRO will continue to identify other studies, which when complete can assist facilities with focus areas to accomplish the greatest impact. Two studies performed this year, the PGY >24 consecutive hours and surgical exemption study, provided such opportunity.
- Management staff will work with the facility's program organization staff; i.e., program directors, program support coordinators, etc., to clarify understanding of regulations and needs of the review staff during the survey process.
- IPRO will collaborate with the residency program's primary and affiliated rotation sites to ensure they understand their responsibility for ensuring compliance.
- 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.

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 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	Compliance Assessment – Work Hour Complaint Visits
Exhibit 18	Compliance Assessment – Hospital Re-Visits

Exhibit 19 Compliance Assessment – Annual and Specialty Area Compliance Trend **Appendices**

Appendix A

Appendix A contains the following comparison exhibits based on total visits conducted at facilities in Year one and two:

Exhibit 20	Year 1- 3 Comparisons Assessment - Annual Compliance Visits Statewide by Month
Exhibit 21	Year 1- 3 Comparisons Compliance Assessment- Statewide Annual Compliance Visits
Exhibit 22	Year 1- 3 Comparisons Compliance Assessment- Regional Annual Compliance Visits
Exhibit 23	Year 1-3 Comparisons Compliance Assessment- Statewide Distribution of Findings
Exhibit 24	Year 1- 3 Comparisons Compliance Assessment- New York City Region Distribution of Findings
Exhibit 25	Year 1- 3 Comparisons Compliance Assessment- Lower Hudson Valley & Long Island Region Distribution of Findings
Exhibit 26	Year 1- 3 Comparisons Compliance Assessment- Central Region Distribution of Findings
Exhibit 27	Year 1- 3 Comparisons Compliance Assessment- Western Region Distribution of Findings
Exhibit 28	Year 1- 3 Comparisons Compliance Assessment- Northeast Region Distribution of Findings
Exhibit 29	Year 1-3 Comparisons Compliance Assessment- Statewide >24 by Region
Exhibit 30	Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Facility Bed Size
Exhibit 31	Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Program Size
Exhibit 32	Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Specialty
Exhibit 33	Year 1- 3 Comparisons Compliance Assessment- Statewide Complaint Visits
Exhibit 34	Year 1- 3 Comparisons Compliance Assessment- Statewide Re-Visits

* 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.