

Working Hours and Conditions Post-Graduate Trainees Annual Compliance Assessment Contract Year 4 10/1/04-9/30/05

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 and a one-year extension with the DOH, IPRO conducted compliance assessments at all teaching hospitals. A total of 158 compliance visits were conducted in the fourth year of the contract from October 1, 2004 to September 30, 2005, which included annual compliance visits at all 118 teaching facilities in New York State, 12 complaint investigations, and 28 re-visits. In total, the working hours of more than 8,436 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 four of the Post-Graduate Trainees Working Hour Compliance Assessment Program, include the following:

- Annual compliance reviews were conducted at all 118 teaching facilities, with 104
 hospitals found in substantial compliance with requirements and 14 hospitals cited for
 non-compliance in at least one program area
 - In eight (8) of the facilities cited, only one (1) program area within the facility evidenced non-compliance
 - In four (4) of the facilities cited, two (2) program areas within the facility evidenced non-compliance
 - In one (1) of the facilities cited, three or more program areas within the facility evidenced non-compliance
 - In one (1) of the facilities cited, the Graduate Medical Education department within the facility evidenced non-compliance
 - 12 on-site complaint investigations were conducted with a 17% substantiation rate
 - Six (6) of the 12 complaints related to surgical programs with two (2) complaints substantiated
 - Three (3) of the 12 complaints related to internal medicine programs with no complaints substantiated
 - Three (3) of the 12 complaints were related to one complaint each in anesthesia, ob/gyn, and pediatric programs with the complaints not substantiated

- In follow-up to identified non-compliance, 28 re-visits were conducted to monitor the facility's plan of correction (POC) implementation
 - 89% of re-visits evidenced substantial compliance
 - 11% of re-visits evidenced at least one element of continued non-compliance
 - 21 re-visits focused on surgical compliance issues with 10% continued noncompliance, and 15 revisits focused on internal medicine compliance issues with 13% continued non-compliance
- 13 of the 158 (8%) compliance reviews conducted evidenced residents working more than 24 consecutive hours
 - Programs in surgery (69%) and internal medicine (25%) were most frequently cited in this area
- Seven (7) of the 158 (4%) compliance reviews conducted evidenced residents not receiving one full 24-hour off period each week
 - Programs in surgery (55%), followed by ob/gyn and pediatrics at 18% each, and internal medicine at 9% were most frequently cited
- Three (3) of the 158 (2%) compliance reviews conducted evidenced improper separation between working assignments
 - Programs in surgery (75%) and internal medicine (25%) were most frequently cited
- One (1) of the 158 (1%) compliance reviews conducted evidenced residents working more than 80 hours averaged over four weeks
 - All programs cited were in surgery

Annual Compliance Assessment

Exhibits 1 - 2 / Implementation

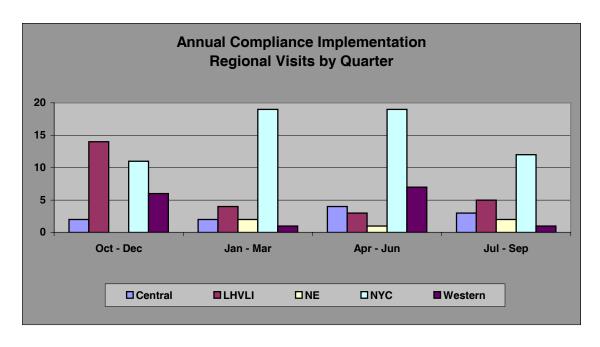
Exhibit 1 illustrates the 118 annual reviews for the fourth year of the contract conducted between October 2004 and September 2005.

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, 14 (12%) 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 14 facilities cited for non-compliance, nine (9) evidenced non-compliance in only one program area, four (4) of the facilities cited evidenced non-compliance in two program areas, and one (1) facility evidenced non-compliance in three or more program areas.

Exhibit 3

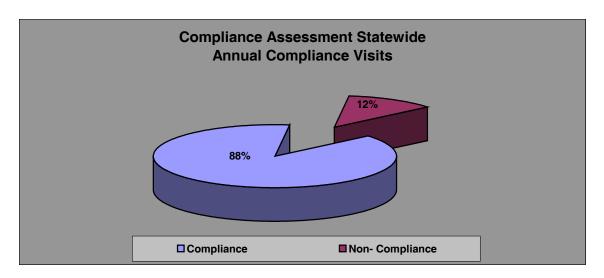
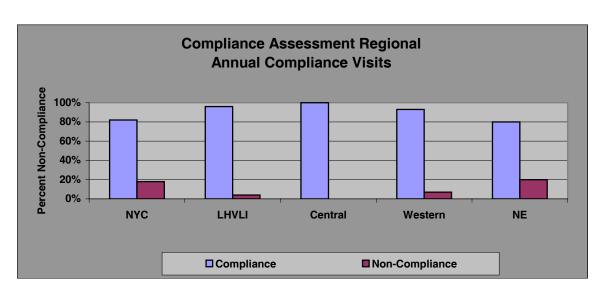


Exhibit 4



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 2004 and September 2005.

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

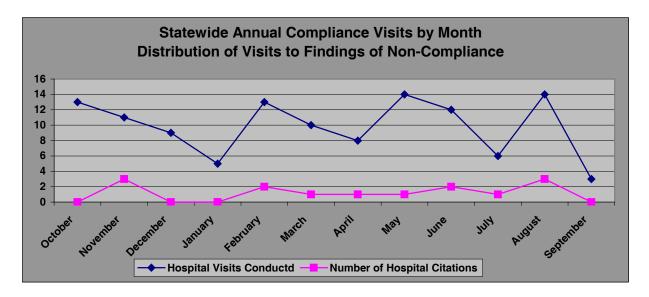
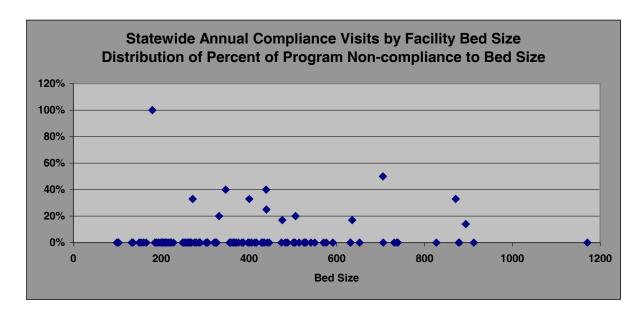


Exhibit 6 presents a detailed assessment of compliance by bed size for the 118 annual visits. Each facility is identified by its bed size, and is evaluated by the percent of non-compliance, as evidenced by the percentage of facility programs that were cited for non-compliance. For example, a facility 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



One percent (1%) of the annual visits conducted evidenced some level of non-compliance in every teaching program reviewed at that site. In contrast, 99% 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 four of the contract, 12% 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 four of the contract, one 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 six percent (6%) 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. Four percent (4%) 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. Two percent (2%) of facilities reviewed during year four were cited for deficiencies in their QA/QI performance. It should be noted that QA/QI would automatically be cited in year four for any facility that had a repeat deficiency from year three or in the case of a year four re-visit, a repeat of findings in year four.
- 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 four 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 four, 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 four.
- 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

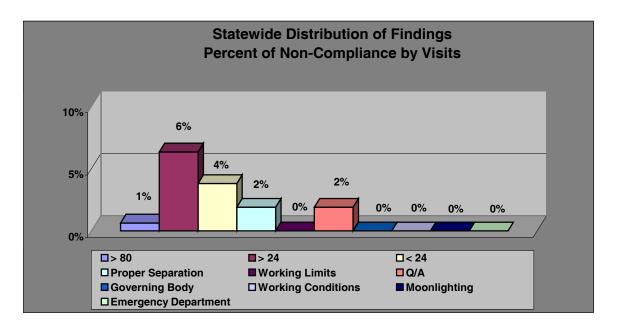


Exhibit 8

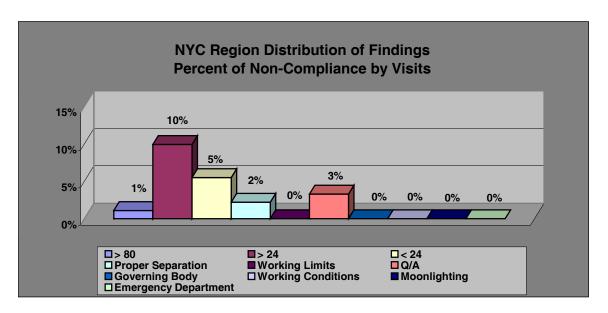


Exhibit 9

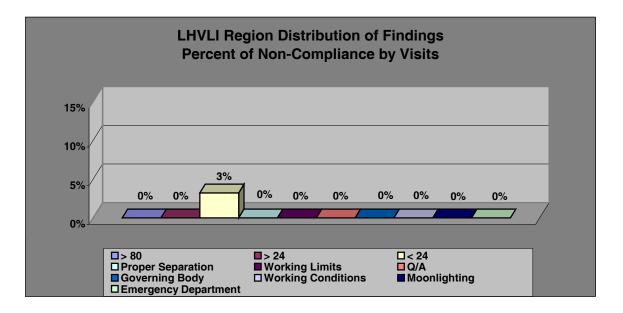


Exhibit 10

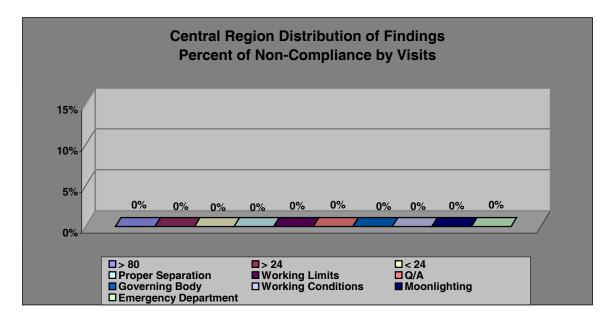


Exhibit 11

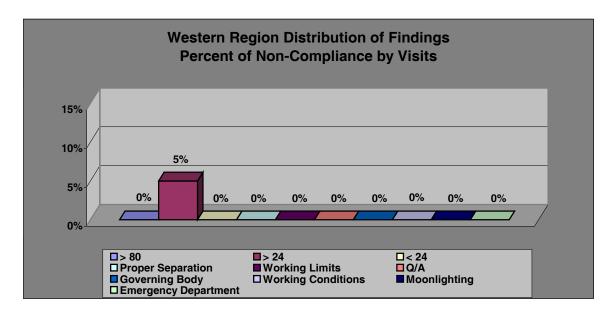
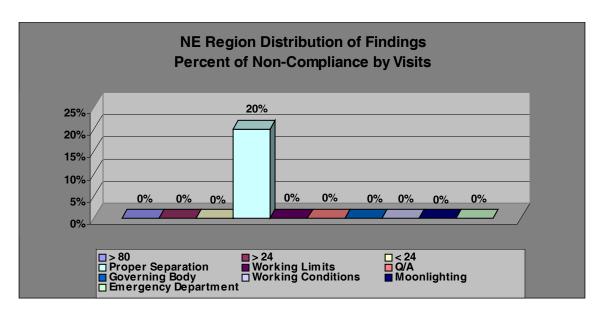


Exhibit 12



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 four of the contract, this area was the most frequently cited. Statewide, non-compliance was evidenced in 6% 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, 10% 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 Western at 5%, and LHVLI, Northeast and Central at 0%.

Exhibit 13

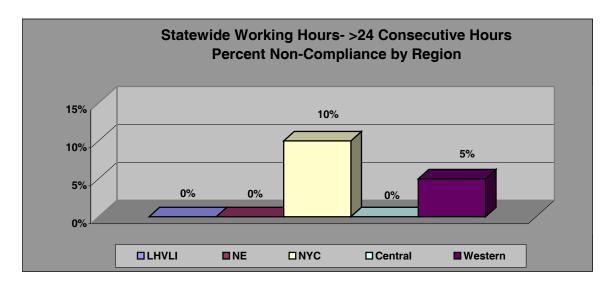
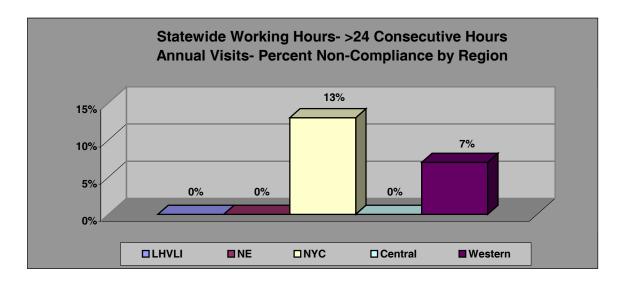


Exhibit 13a – In comparison, this exhibit is based upon the 118 annual visits performed. During the annual visit, New York City had 13% of facilities out of compliance with this work hour regulation. The findings for the remaining regions are Western at 7%, and LHVLI, Northeast and Central at 0%.

Exhibit13a



Exhibits 14 & 15 correlate findings to facility bed size and program size (number of residents) in a facility program. The highest percentage of findings for >24 hours was found in facilities with 401-600 beds for all visits, while the percentage was equal with facilities with 601+ beds for annual visits. The highest percentage of findings for >24 hours was found in facilities with between 301-500 residents in the facility teaching program, closely followed by facilities with between 101-300 residents for all visits and 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

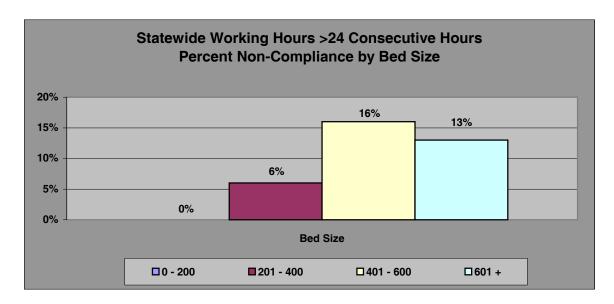


Exhibit 14a

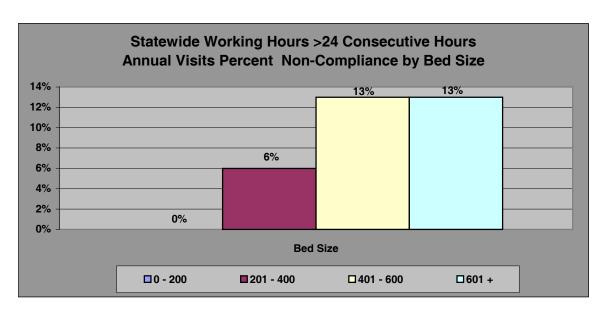


Exhibit 15

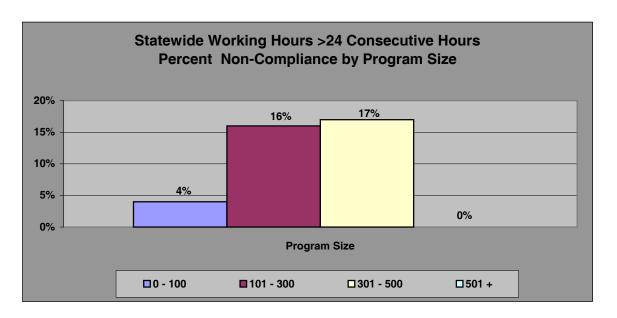
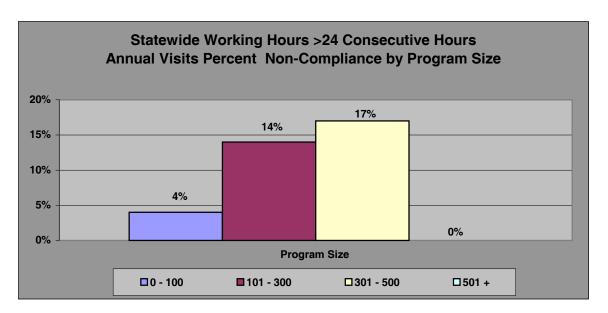
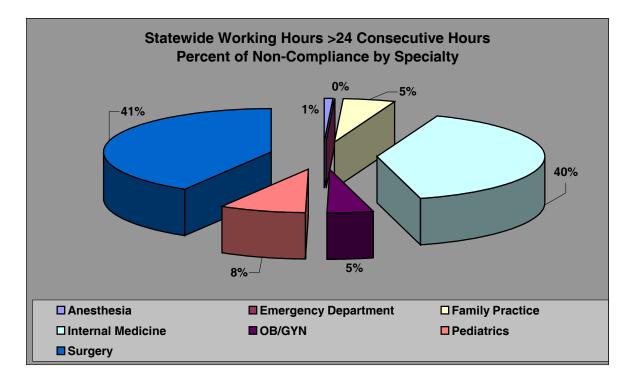


Exhibit 15a



As illustrated in Exhibit 16, based upon the 158 total visits conducted, surgery at 41% and internal medicine at 40% 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 four of the contract, the DOH received 12 working hour complaints. Exhibit 17 indicates that 17% of complaints were substantiated following investigation. Six (6) of the 12 complaints related to surgical programs with two (2) of these complaints substantiated. Three (3) of the 12 complaints were specific to internal medicine programs and were not substantiated. One (1) complaint each related to anesthesia, ob/gyn, and pediatric programs were 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 12% non-compliance findings at annual compliance visits, at revisit, 89% of facilities were found in substantial compliance and 11% of facilities continued to evidence at least one element of non-compliance (Exhibit 18) at the time of the re-visit.

Exhibit 18

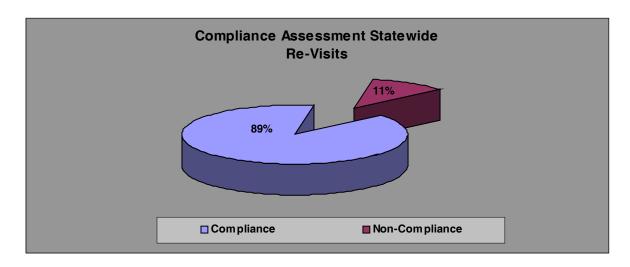
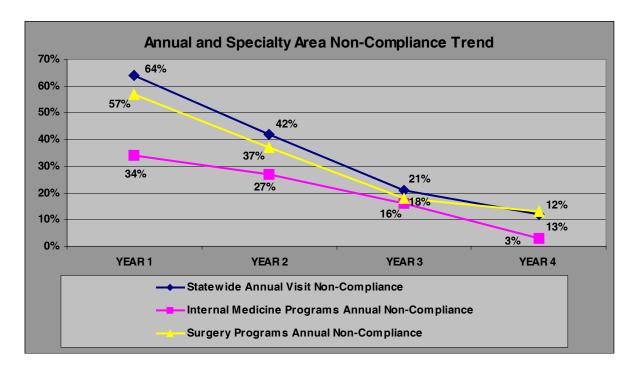


Exhibit 19 / Compliance Assessment - Annual and Specialty Area Compliance Trend

Throughout the four 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.

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 in surgery, and substantial improvement has been made in the internal medicine program in year 4.

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 four 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 non-compliance 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 fourth contract year was completed September 30, 2005. During the next contract 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 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 to date, 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.
- IPRO will continue to provide formal and informal education to assist facilities in achieving compliance.
- IPRO will continue to review schedules, as requested by facilities, to assist them in achieving compliance.

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
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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 Non-Compliance Trend

Appendices

Appendix A

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

Year 1- 3 Comparisons Assessment - Annual Compliance Visits Statewide by Month
Year 1- 3 Comparisons Compliance Assessment- Statewide Annual Compliance Visits
Year 1- 3 Comparisons Compliance Assessment- Regional Annual Compliance Visits
Year 1-3 Comparisons Compliance Assessment- Statewide Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- New York City Region Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- Lower Hudson Valley & Long Island Region Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- Central Region Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- Western Region Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- Northeast Region Distribution of Findings
Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Region
Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Facility Bed Size
Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Program Size
Year 1- 3 Comparisons Compliance Assessment- Statewide >24 by Specialty
Year 1- 3 Comparisons Compliance Assessment- Statewide Complaint Visits
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.