

John,

The large increase of burden hours for the Opioid Regulations (OMB No. 0930-0206) is due to the patient exceptions that require Programs of Opioid Treatment Programs (OTPs) to submit a patient exception form if a patient would like an exemption under 42 CFR 8.11(h). This program requirement was modified with the final rule in 2003; however, the OTPs have been slow to incorporate all of the changes. The program has continually educated the OTPs and this has led to a higher number of submissions of the SMA-168. Additionally, SAMHSA began counting every submission by fax and by the web. Previously, SAMHSA based their numbers on a sample of the actual submissions and the numbers were underestimated.

Please let me know if you need any other questions answered.

Thanks,

**Summer King**  
**Survey Statistician/  
OMB Clearance Officer**  
**SAMHSA/OAS**  
**Room 7-1045**  
**1 Choke Cherry Road**  
**Rockville, MD 20850**  
**Phone: 240-276-1243**  
**Fax: 240-276-1260**