The Title 22 Wavier Process

First let me apologize. For those of you who are not from California, or are unaware of the struggle that we face here, I present a not so brief recap.

Although Title 16 of the California code of regulations (CCR) authorizes the physician assistant to act as a first or second assistant in surgery under the supervision of a supervising physician\(^1\), PA’s are further restricted by CCR Title 22, Division 5, Article 6, §70435 (b)(2) from acting as first assistant surgeon for cardiac surgery requiring extracorporeal bypass. The dates back to an arcane regulation that was written in the early 1970s, and requires that the surgical team for extracorporeal bypass procedures include a minimum of three surgeons\(^2\). PA’s are allowed to function as second assistant surgeon under a waiver process to this regulation. Each cardiac surgery program must individually apply for this waiver to use the PA’s in this role.

So why don’t we just simply Change Title 22?

The truth is that because of this regulation, California is the only state in the United States where surgeons and hospitals can bill for three surgeons at the table for an on-pump case. Attempts to convince surgeons that their reimbursement for a second assistant surgeon is minimal and that neither Medicare nor Medi-Cal (the state’s version of Medicaid) pay this reimbursement, and that this should not be a reason for not changing the regulation, have been unsuccessful. Additionally, any PA regulation changes meet with very organized resistance from the California Nursing Association. Attempts to change Title 22 by the California Association of Physician Assistants (CAPA) many years ago required the expenditure of significant resources, and CAPA, although supportive of our efforts, has shown in unwillingness to give us a significant support in this quest. The only waiver ever granted to the first assistant surgeon provision was given to Kaiser back in 1993, under the guise of performing a study. But, to this date no data has ever been collected by Kaiser nor has any study been produced. Requests for waivers for small community hospital programs have gone unanswered by the state.

Since starting in cardiac surgery in 1998, when I found out that I could not legally first assist pump cases, it is been my mission to find a path that subverts this regulation. For the last 12 years, the APACVS has supported me in this quest. For the past several years, the AAPA has been leading a task force of which I have been a member, to address the inadequacies and improprieties of Title 22. The rewriting of Title 22

\(^1\) CCR Title 16, Division 13.8, Article 4, §1399.541(i)(2)
\(^2\) CCR Title 22, Division 5, Article 6, §70435(b)(2). “A minimum of three surgeons shall constitute a surgical team for the performance of all cardiovascular operative procedures which require extracorporeal bypass. At least one surgeon must meet the requirements outlined in subparagraph (b)(1) above.”
is inevitable. Title 22 is a massive regulation that regulates all of healthcare throughout California. From the small standalone health clinic to nursing homes and hospitals, Title 22 dictates how they function and address the needs of patients in California. If one were to place binders containing the volumes of regulations within Title 22 on a table, it would stretch out over 6 feet in length. A rewrite is underway of the entire Title 22 regulation, from end-to-end, but this is estimated to require a decade’s worth of work. APACVS, and AAPA have taken steps to make sure that we are at the table when our little section of Title 22 is revised. The cost of healthcare, and the availability of qualified assistant surgeons, will necessitate a change in this regulation. But, we can’t wait that long. We undertook a decision as a task force that we would pursue a waiver to the regulation as an interim solution.

In September 2016, Dr. Li Poa, Director of Cardiac Surgery at Providence Little Company of Mary Hospital in Torrance California submitted a formal waiver request to the state of California to allow the three PAs to act as first assistant surgeon for cardiac cases requiring extracorporeal bypass. This was not the first attempt to request this waiver. In 2007, Dr. Li Poa and I requested such a waiver while at Enloe Medical Center in Chico California. The response from the state at that time was that there was no data to prove that PAs were safe and efficient assistant surgeons in this role. When we appealed, citing that California was the only state in the US that did not use PAs as first assistants for extracorporeal bypass cases, and that the PAs that were requesting the waiver had all first assisted these cases out of state, the state of California replied that it didn’t matter what other states were doing. There was no evidence to support the waiver request. In response, we undertook a retrospective review of about 1,000 cases over a four-year period to compare outcomes between PA first assistant surgeons and MD first assistant surgeons. PAs first assisted 21% of the on-pump cases in that small, single center study. The study concluded that there was no difference for nine performance factors and 26 complications when PAs were used rather than MDs as first assistant surgeons. The response of the state to the publication of this study was to audit Enloe Medical Center to ensure that the PAs had not been operating outside our scope of practice. The waiver was not granted. Nor, has the waiver been granted for Providence Little Company of Mary. Instead, the state has delayed and has not made a decision.

Our President, Steve Gottesfeld, has written in this issue to outline our plans to continue this fight. One of those strategies is to open the flood gates and ask other programs to file for waivers. Our hope was that once the first waiver was granted, it would present a path for other programs to follow and we would provide a template and assistance to those programs in the waiver process. We are hoping that flooding the state with multiple requests will force their hand to grant waivers. At a minimum, we’re hoping that they will be required to make a decision, even if that decision is “no.” To date, they have only delayed a decision on the waiver before them. A “no” decision helps to build our case with the Federal Trade Commission.

To understand the waiver process, one must consider where the waiver to act as a second assistant surgeon originates. For California PAs, the waiver that allows you to harvest and to act as second assistant during cardiac surgery is granted at the county level. Therefore, your hospital, or your program director, must apply for waiver through your county health department.

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The “Advocacy” tab on the APACVS website is where you will find the waiver template. The template consists of two documents, the waiver application itself, and a credentialing policy for your local hospital program. The waiver template contains a number of bracketed instructions in red that need to be filled in by your program. There are also a number of attachments that need to be sent with the waiver, including a CV for each PA that is requesting a waiver.

The second document outlines the training and education requirements that will be documented and maintained by your hospital to support your credentialing to first assist for extracorporeal cases. You will need to establish a similar policy with your hospital. Those requirements are summarized in the next paragraph.

PAs wishing to act as first assistant surgeons for cardiac surgery must be licensed by the state of California and certified by the National Commission on the Certification of Physician Assistants (NCCPA). They must complete 50 cases as a second assistant surgeon or have graduated from an accredited postgraduate surgical residency program. They must have five proctored cases as a first assistant surgeon for cardiac surgery. Documentation of the 50/5 case requirement requires a letter from your supervising surgeon. If you started in the cardiac surgery specialty after January 1, 2017, then those cases must be logged as well. Fellow members of the APACVS and those PAs who have earned a Certificate of Additional Qualification (CAQ) from the NCCPA, in cardiothoracic surgery, are considered to have satisfied the 50 case requirement, as they have provided documentation that exceeds these requirements in order to attain those credentials.

In closing, this has been a long struggle, and it continues. But, now it’s your chance to become part of that struggle and help us finally put to rest this regulation that prevents you from operating at your full potential and prevents your surgeon from selecting the best possible team to address the patient’s needs. We encourage you to print out the waiver template and the credentialing policy and to discuss this with your surgeons and to submit to the state as soon as possible. Assistance with the waiver process is available. You can always contact me at ranz@earthlink.net. Additionally, you can contact the executive director of the APACVS, our former president David Lizotte at dlizotte39@gmail.com. Finally, the APACVS will continue to work directly with AAPA on your behalf.