Joint Commission on Health Care

SUMMARY OF PUBLIC COMMENTS RECEIVED

Regulation of Surgical Assistants and Surgical Technologists
SB 313 – Senator Harry B. Blevins

Cost Sharing and Specialty Tier Pricing of Prescription Medications
HJR 579 (2011) – Delegate John M. O'Bannon, III

Public Comment Summary
Regulation of Surgical Assistants and Surgical Technologists

Sixty-one comments were received regarding the policy options addressing the regulation of surgical assistants and surgical technologists. Comments were submitted by:

- **Surgical technology students and instructors from Sentara College of Health Sciences**
- **Physicians and surgical technologists from the University of Virginia Health System**
- Catherine Sparkman, Director of Public and Government Affairs, **Association of Surgical Technologists**
- Karen Ludwig, **Association of Surgical Assistants**
- Paul Collicott, **American College of Surgeons**
- Mary Catherine Flynn, CST, Secretary of the **Virginia Commonwealth State Assembly of Surgical Technologists**
- Calvin Bailey, **Professional Development Specialist for STs and SAs at Mary View Medical Center**
- Linda Starks, **Program Director, Fortis College**
- J. Craig Merrell, MD, President, **American Society of Plastic Surgeons**
- David Jeanette, CSA, President, **Virginia Association of Surgical Assistants and the National Association of Surgical Assistants**
- Virginia Rawls, **CST, Program Director, Riverside School of Health Careers**
- **CSTs, CSAs and MDS from Centrahealth Lynchburg General and Virginia Baptist**
- Dedra Parrish, **Director of ST, ECPI University**
- **Private physicians**
- Katherine Webb, Senior Vice President, **Virginia Hospital and Healthcare Association**

	Options	In Support
1	**Provide a written report** to the House Committee on Health, Welfare and Institutions **without taking further action**.	**1** VHHA
2	**Provide a written report** to the House Committee on Health, Welfare and Institutions **with a letter indicating that the Joint Commission voted in support of certification of surgical technologists** as outlined in SB 313.	**60**
3	**Provide a written report** to the House Committee on Health, Welfare and Institutions **with a letter indicating that the Joint Commission voted in support of licensure of surgical assistants** as outlined in SB 313.	**60**

Comment Excerpts

The 60 letters written in support also included 300 signatures from physicians who had indicated their support for the regulation of surgical technologists and surgical assistants when the Virginia Department of Health Professions completed a study in 2010. The majority of letters in support touched on similar themes:

- Surgical technologists and surgical assistants are the only members of the operating room team that have no minimum educational or training requirements and patients expect everyone in the surgery room to have a minimum level of training and education.
- Because surgical technologists are currently unregulated, hospitals determine the level of credentialing necessary for a surgical technologist's employment. This results in a hodgepodge of different requirements that are confusing for individuals who wish to practice as surgical technologists.
- Given the tasks surgical technologists perform in the operating room, there is a risk to Virginia's patients.
- The Virginia Department of Health Professions conducted a thorough study and recommended regulation.
- Physicians rely on surgical technologists and surgical assistants, and they also rely on hospitals for staffing. As such and because they are ultimately legally responsible, they want to feel confident that every member of the operating room has been properly educated and trained.
- Other professions, such as manicurists and massage therapists, pose less risk to Virginia consumers are regulated.
- There is no fiscal impact to the Commonwealth of Virginia or Virginia's hospitals.

Katherine Webb, Senior Vice President of the Virginia Hospital and Healthcare Association submitted a letter in opposition to the regulation of surgical assistants and surgical technologists. Ms. Webb stated that "regulation of these practitioners is unnecessary, raising obstacles to care delivery that increase health care costs and restrict workforce flexibility without enhancing patient safety or care quality.

- Staff qualifications, training, performance and quality of care in hospital surgical services are regulated by The Joint Commission, the Centers for Medicare & Medicaid Services' Condition of Participation, and Virginia's hospital licensure regulations enforced by the State Board of Health.
- Surgical assistants and surgical technologists practice under the supervision of licensed surgical staff. They do not engage in autonomous practice.
- There is no documented evidence of patient harm in Virginia hospitals supporting regulation of these practitioners.
- …the hospital and its licensed surgical staff are legally and professionally responsible for the practice and actions of surgical assistants and surgical technologists, and therefore they have strong incentive to ensure that the assistants and technologists they hire and supervise have the necessary qualifications and skills. Doing otherwise exposes the hospital and licensed surgical staff to significant legal liability.
- …Hospitals are engaged in increasingly comprehensive and transparent patient safety programs that measure and disclose outcomes and quality. These efforts increase hospitals' incentives to use highly competent professionals in surgical settings.…"

Public Comment Summary
Cost Sharing and Specialty Tier Pricing of Prescription Medications

Ten comments were received regarding the policy options addressing cost-sharing and specialty tier pricing prescription medications. Comments were submitted by:

- Keenan Caldwell, State Government Relations Director, **American Cancer Society Cancer Action Network (ACS CAN)**
- **Susan Keitt**
- Ashley Chapman, Virginia Statewide Advocacy Manager, **National Multiple Sclerosis Society – Central Virginia Chapter**
- Jen Johns, MPH, Associate Director, State Government Relations, **National Patient Advocate Foundation (NPAF)**
- James Romano, Director of Government Relations, **Patient Services Incorporated (PSI)**
- **Philip Posner, Ph.D.**
- **Susan Teabout**
- Becky Bowers-Lanier on behalf of the **Virginia Alliance of Medication Affordability and Access (VAMAA).** VAMAA represents:
    - Virginia Hemophilia Foundation – Hemophilia Association of the Capital Area
    - National Multiple Sclerosis Society
    - Virginia Organization Responding to AIDS
    - Patient Services Incorporated
    - Health HIV
    - Arthritis Foundation Mid-Atlantic Region.
- Doug Gray, Executive Director, **Virginia Association of Health Plans**
- Susan R. Rowland, MPA, Executive Director, **Virginia Organization Responding to AIDS**

	Options	**In Support**	
1	Take no action.	**1**	VAHP
2	Include **study in the JCHC 2013 work plan** in order to review the effects of PPACA, if retained, on cost-sharing and specialty tier pricing of prescription medications.	**7**	ACS CAN NMSS NPAF PSI VAMAA VORA VAHP (or Opt. 1)
3	**Request by letter of the JCHC chair that the Virginia Association of Health Plans (VAHP) encourage health insurance carriers to offer monthly payment plans** for enrollees who are required to purchase multiple months of a high-cost prescription at one time.	**6**	ACS CAN NMSS NPAF PSI VAMAA VORA
4	**Introduce legislation or budget language to prohibit coinsurance** (i.e., percentage cost of the prescription) as the basis for cost sharing for outpatient prescription drug benefits, **and limit a health insurance enrollee's co-payment for each outpatient prescription drug to $150 per one-month supply** or its equivalent for prescriptions for longer periods, adjusted for inflation over time.	**8**	ACS CAN NMSS NPAF PSI Philip Posner, Ph.D. Susan Teabout VAMAA VORA
5	**Introduce legislation requiring** qualified health plans to allow individuals who are expected to incur costs in excess of the cost sharing limits set by the ACA **the option of paying their capped out-of-pocket amount in 12 equal installments** over the course of the year.	**8**	ACS CAN Susan Keitt NMSS NPAF PSI Philip Posner, Ph.D. VAMAA VORA
6	***Introduce legislation*** *to require qualified health plans* ***to notify individuals in writing at least 60 days prior to a change in the tier status of their medications.***	***3***	*ACS CAN* *PSI* *VAMAA*

Comment Excerpts

Three individuals (**Susan Keitt, Philip Posner, Ph.D., and Susan Teabout)** who require specialty prescription medication to treat their multiple sclerosis offered public comments regarding their experiences.

Ms. Susan Teabout explained her hope that the out-of-pocket costs of specialty tier prescription drugs will be limited by writing, in part:

"At the time of diagnosis [in December 2002], I was President of Delta Connection Academy, a subsidiary of Delta Air Lines. I managed 5 pilot training locations and contracts for airline pilot training with airlines throughout the world….My Multiple Sclerosis progressed and by September of 2005, I left Delta Air Lines due to my disabling condition.

Life is made of defining moments and leaving my dream career due to Multiple Sclerosis was clearly one of those 'moments.' I was amazed at the number of people who came forward telling me they suffered from Multiple Sclerosis or had a close friend or family member who suffered from the disease. One very common and sad theme emerged. Most could not afford the high cost of the MS disease-modifying drugs, which fall into the "specialty tier pricing" category and cost over $40,000 annually. As a result, they are not on any MS therapy and their disease most likely will progress faster. While "specialty tier pricing" may have seemed like a solution, I can tell you both personally and professionally, it is the wrong approach and it simply does not work….my insurance provider, paid $46,810.98 on my behalf in 2011. My 2011 out of pocket costs were significantly lower than 2010 because I began to take the MS drug only 2 times a week versus the 3 recommended. Unfortunately, this decision means my MS will progress faster. I simply could not afford my medical costs exceeding $15,000 annually, as the cost of the MS drugs continue to escalate. For 2012, I continued to take my MS drug...two times a week and I began taking an additional MS drug…which costs over $1,000 monthly.

…Having run a division of a large company, I understand first-hand the tremendous pressure to cut spending. My hope is that Legislators will ask themselves before any vote, 'Would I hold the same position, if tomorrow I knew a close family member or myself would need to take a "specialty tier drug" that exceeds $40,000 annually?' Trust me…. I never imagined in a million years as a world-class athlete, a pilot, and ranked in top 30 fastest women motorcycle racers, that I would need to take a "specialty tier drug" that was financially unaffordable to slow the disease progression of become fully disabled. My hope is Legislators will take a much closer look at 'specialty tier pricing' and limit the out-of-pocket cost of prescription drugs. I sincerely appreciate the Joint Commission's efforts to study and communicate their findings regarding cost sharing and specialty tier pricing of prescription drugs more than you will ever know."

The American Cancer Society Cancer Action Network, National Patient Advocate Foundation and the Virginia Alliance of Medication Affordability and Access (which represents **the Virginia Hemophilia Foundation – Hemophilia Association of the Capital Area, National Multiple Sclerosis Society, Virginia Organization Responding to AIDS, Patient Services Incorporated, Health HIV, Arthritis Foundation Mid-Atlantic Region), wrote in support of Options 2 through 5**.

In addition, **several of these organizations commented in support of an Option 6** to require qualified health plans to notify individuals in writing at least 60 days prior to a change in the tier status of their medications. At the time of the study, it was thought that this Option would not be needed if federal health reform were to be retained. However, in subsequent discussions, U.S. Department of Labor staff clarified that proposed health reform regulations do not address these types of notifications.

Virginia Association of Health Plans commented, in part:

"If the ACA out-of-pocket limits remain in effect and there are very few Virginians who have 4th tier drug benefits that treated specialty drugs differently from other prescriptions, VAHP sees no need for further state action unless federal action is determined to be inadequate.

Policy suggestions to spread out a member's payments for coinsurance and deductibles may not be workable or of assistance to the patient.

Maximum out-of-pocket limits help protect members from unlimited risk and costs. When these limits are spread out further, the member takes longer to reach his/her limit, exposing him/her to more risk longer. Delaying meeting the out-of-pocket limit is not helpful to the member.

Payment collection of coinsurance and deductibles is a provider function. These are amounts due to the provider not the health plan. Health plans are not in the position to address provider payment responsibilities. These are between the patient and his/her provider.

VAHP commends the JCHC on its research on cost sharing and specialty tier pricing of prescription drugs. However, since concerns with cost-sharing are addressed by the ACA and there are very few individuals covered under 4-tier drug benefits, VAHP recommends either Option 1 – take no action or Option 2 – to review the effects of the ACA on cost sharing and specialty tier pricing of prescription medications."