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COMMITTEE CHAIRPERSON AND MEMBERS OF THE COMMITTEE:

I am here to speak in favor of Proposed House Bill 6158, An Act Concerning Vaccine Distribution. I am Dr. Robin Oshman, a Dermatologist from Westport, CT. I am an Asst. Clinical Professor in the Dept. of Dermatology at Yale New Haven Hospital, Vice President of the Fairfield County Medical Association, and President of the Women's Medical Association of Fairfield County – a branch of the American Medical Women's Association.

On January 1, 2013 the statutory "vaccine supply" Mandate in Public Act 12-1 became law. There was no public hearing concerning this law despite the fact that the health and well-being of all of the children in the state are affected by it.

Connecticut has one of the highest childhood vaccine rates in the country. Why has our state government decided to fix something that did not need fixing?

As a result of this law doctors are not permitted to administer vaccine to children 18 years and under unless they sign an egregious contract with the Department of Public Health. Many doctors have stated that

they will not sign on.

Pediatricians are not the only specialty affected by this vaccine mandate. I am a dermatologist. I will not be signing a contract with the Department of Health. As a result, should a child come to my office after stepping on a rusty nail I will be able to treat the wound. However, I will no longer be permitted by law to vaccinate this child against tetanus. I will advise the parent of the need for this vaccine and refer the child to someone who has signed on. Once this child leaves my office there is no guarantee that the parent will go elsewhere for the vaccine. This child is now “lost to follow up” and in danger of contracting tetanus.

The gynecologists administer the HPV (Human Papilloma Virus) vaccine to teenagers. Many gynecologists will not sign these contracts and, as a result, will not be permitted to administer this vaccine. The purpose of this vaccine is to prevent cervical cancer.

Prohibiting doctors by law from practicing a form of medical treatment i.e. administering vaccine to our most vulnerable population - our children, unless a contract is agreed to and signed with the Public Health Department is both dangerous for our population and unfairly restricts the practice of medicine in the State of Connecticut.

Physicians should have the option of participation in this vaccine mandate program. Doctors should be allowed to procure vaccine privately and when the need arises to vaccinate children without the barriers imposed by this mandate.



# Fairfield County Medical Association

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November 7, 2012

## Review of the Connecticut Vaccine Program Provider Agreement

During the 2012 legislative session, the Connecticut General Assembly passed a budget implementer bill which requires all health care providers, including physicians, who inoculate children to procure free of charge all applicable vaccines from the State of Connecticut effective January 1. In order to participate in the Connecticut Vaccine Program a physician must sign and return to the Connecticut Department of Public Health a *Connecticut Vaccine Program Provider Agreement*. The members have asked the Fairfield County Medical Association to provide comments on the *Connecticut Vaccine Program Provider Agreement* that the Department of Public Health included in the September 28, 2012 Immunization Program materials that DPH issued to Connecticut physicians. The FCMA's General Counsel, Garfunkel Wild, P.C., reviewed the *Provider Agreement* and provided us with comments which are summarized below.

### I. Background

#### A. The Statutory "Vaccine Supply" Mandate in Public Act 12-1

Section 212 of Public Act 12-1 mandates that DPH be the supplier of childhood vaccines as of January 1, 2013. The new vaccine law is summarized by DPH in its September 28 cover memorandum to Connecticut health care providers as follows: "[R]evisions to CT General Statutes 19a-7f implemented during this past legislative session now require that beginning January 1, 2013 all health care providers who administer vaccines to children from birth through 18 years of age obtain those vaccines through the Connecticut Vaccine Program."

Section 212 provides an exception from the mandate during times of public health emergencies, disasters, and a declared national or state vaccine shortage. The provision also includes an exception that permits a health care provider to use a vaccine that is not supplied by DPH "if, based upon the provider's medical judgment, (i) administration of such vaccine is not medically appropriate, or (ii) the administration of another vaccine that [DPH] is not authorized to supply ... is more medically appropriate."

The vaccine serum that DPH will be supplying to providers will be at no purchase cost to the providers. The new vaccine law permits health care providers to charge a fee for administering a vaccine; however, it prohibits providers from selling or seeking or receiving remuneration for the vaccine serum.

To date, no regulations relating to the implementation of the program have been promulgated under the ordinary and longstanding rule-making process established by Connecticut law, which typically involves a notice and comment period and an opportunity for public hearing.

#### B. The *Provider Agreement*

The packet issued by DPH on September 28 includes a *Connecticut Vaccine Program Provider Agreement* which, according to DPH's September 28 cover memorandum, "must be completed and submitted to enroll in the Connecticut Vaccine Program." In addition, the DPH memorandum warns: "All health care providers who administer vaccines to children birth through 18 years of age should enroll before December 1, 2012 in order to have vaccine on-hand to administer on January 1, 2013."

## II. Comments Regarding *Provider Agreement*

### A. Legal and Administrative Issues

***The following is a list of legal and administrative issues concerning the Provider Agreement. These points are of a general nature and should not be considered legal advice as they are made without consideration of circumstances that are specific to any particular health care provider, physician, or medical practice. A physician should review the Connecticut Vaccine Program Provider Agreement with legal counsel before signing and returning the Provider Agreement to DPH.***

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1. As a threshold matter, there are serious questions about the legality of Section 212 of Public Act 12-1, which in turn implicate the legality of the *Provider Agreement*. The new vaccine law may, among other arguable legal deficiencies: (i) constitute an illegal impairment of the private right to contract, as it interferes with existing contracts between providers and managed care companies and other insurers; (ii) contain provisions that are impermissibly vague or that lack sufficient explanation or detail; and (iii) threaten due process violations to the extent DPH imposes sanctions on physicians who unwittingly violate the law by making interpretations of the law that are at odds with DPH's interpretations, as could happen for example in connection with varying judgments about when it would be medically appropriate to exercise the exception in the statute permitting use of a supplier other than DPH.
2. As noted above, there are presently no regulations in place for the implementation of the new vaccine law. However, the September 28 DPH memorandum and its attached materials, including the *Provider Agreement*, purport to impose conditions and obligations on providers much like regulations would do.
3. Based on FCMA's understanding, the *Provider Agreement* was not and is not open to bona fide negotiation. Thus, to call it an "agreement" is not an entirely accurate description. A true "agreement" is voluntary and involves a meeting of the minds. This is not the case with this *Provider Agreement*. Although a physician can choose not to sign it, that physician would then be prohibited from giving the applicable vaccinations. Thus, in order to vaccinate children, a function already within the scope of affected providers' licenses, the provider is being forced to sign an agreement that has not been fairly negotiated; this is effectively a contract of adhesion.
4. There are numerous sections in the *Provider Agreement* that seem to be included without any statutory authority in the new vaccine law. For example, in Section 1, we are unsure of the statutory authority for the \$21 administrative fee cap for uninsured and underinsured children. In Section 2, it is unclear on what statutory authority DPH is relying to mandate through the *Provider Agreement* that providers provide free care by foregoing an administrative fee due to an inability of the parent or guardian to pay the fee. In addition, in Section 11 there appears to be no statutory authority in the new vaccine law for DPH's imposition of financial liabilities on providers for storage, waste and loss of vaccines regardless of fault. Moreover, there is an absence of any provision for indemnification or other recourse from the state for providers who suffer financial loss due to the fault of the state or to factors beyond the control of providers, such as delivery delays, tainted products, power outages, etc.
5. The prohibition on billing for vaccines in Section 3 of the *Provider Agreement*, like the new vaccine law itself, arguably constitutes an illegal impairment of private contracts between providers and insurers.
6. A number of sections in the *Provider Agreement* require reporting and recordkeeping requirements and consequently impose related administrative burdens and costs that have not been promulgated through the ordinary administrative process for regulations. For example, see the requirements in Sections 4, 5, 14 and 15 of the *Provider Agreement*.

7. The *Provider Agreement* is silent with respect to penalties for any alleged breach of the *Provider Agreement* by providers. As mentioned above, any adverse action against a provider's license is potentially subject to challenge as illegal on several grounds, including the failure to afford due process and the failure to promulgate proper regulations under Connecticut's administrative procedure laws.

8. In the concluding paragraphs after Section 18, the *Provider Agreement* incorporates by reference several "Executive Orders" and other obligations typically applicable to state contractors, including requirements affecting labor employment practices, employment listings, and conduct and procedures in the workplace. It is advisable for a health care provider to review and understand these obligations if he or she is choosing to sign the *Provider Agreement*.

### III. Conclusion

It bears repeating that even though there are a number of potential legal deficiencies as suggested above, providers are obligated to comply with the new vaccine law and to sign the *Provider Agreement* if they wish to administer the applicable vaccines to their patients.

Several members had asked for "reservation of rights" language to consider in the event that they choose to sign the *Provider Agreement*. A sample letter is attached.

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If any FCMA member would like to consider retaining counsel to discuss the details of the new vaccine law or the *Provider Agreement* and the implications for their particular practice, or possible options in connection with the various administrative, legislative and legal circumstances involved in this matter, we would suggest that you contact Pat Monahan and Barry Cepelewicz of Garfunkel Wild, P.C. at 350 Bedford Street, Stamford, CT 06901; (Telephone: 203-316-0483).

Sincerely,



Mark S. Thompson  
Executive Director

PS – Please contact the Association headquarters should you need a copy of the September 28 cover memorandum or the Connecticut Vaccine Program Provider Agreement. Also look in your email box..

[PHYSICIAN LETTERHEAD]

[DATE]

By Certified U.S. Mail, Return Receipt Requested, and by Fax (860-509-8371)

Vincent Sacco, MS  
Immunization Program Manager  
Department of Public Health  
410 Capitol Avenue  
Hartford, CT 06134

Dear Mr. Sacco:

Enclosed is a Provider Agreement, which I have signed, and a Provider Profile, which I have completed, in order to participate in the Connecticut Vaccine Program. Please be advised that by executing and submitting these documents, I do not waive any rights that I or my practice or facility may have to challenge the legality of the Provider Agreement or Connecticut General Statutes Section 19a-7f, as revised and/or substituted by Section 212 of Public Act 12-1 (the "New Vaccine Law"). I expressly reserve any and all rights to challenge the legality of the New Vaccine Law and/or the Provider Agreement or any aspect of the Department's implementation of the Connecticut Vaccine Program. I also reserve any and all rights to seek to collect, recover and/or recoup any costs, liabilities, and/or damages of any kind whatsoever incurred by me or my practice in connection with the New Vaccine Law and/or the Provider Agreement, through any lawful administrative or court proceeding.

Thank you for your cooperation.

Sincerely,

[PRINTED PHYSICIAN NAME BENEATH SIGNATURE]

cc: Matthew Cartter, MD, MPH, State Epidemiologist  
Mick Bolduc, Vaccine Coordinator

Copies mailed to these individuals should also be sent to:  
Department of Public Health  
410 Capitol Avenue  
Hartford, CT 06134