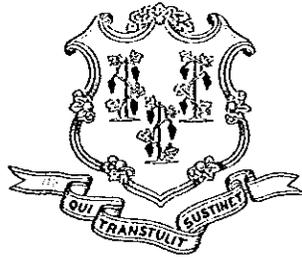


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SENATE
11th District

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Good afternoon Senator Crisco, Representative Megna and members of the Insurance and Real Estate Committee. I am here to testify in support of two bills that are on the agenda today: S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS and S.B. No. 18 AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS

S.B. No. 21 AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS would expand coverage of routine patient care costs for clinical trial patients to clinical trials for serious or life threatening diseases and ensure that third party payers retain their responsibility to patients. In 2001 the Connecticut General Assembly passed PA 01-171 which required insurers to sustain their responsibility to patients who participate in clinical trials for cancer. At that time I expressed my

belief that this coverage requirement should not be limited to cancer but rather should apply to clinical trials for all serious or life-threatening conditions. These courageous patients are willing to take a risk by participating in a clinical trial that is attempting to find more effective treatment for a specific disease. They enter the trial with no expectation that the new treatment will cure their disease. Usually, since most clinical trials are double blind and placebo controlled, patients do not even know if they are receiving the experimental drug or a placebo until the results of the trial are known. These patients are, in a profound sense, heroes and heroines. They are taking a risk to help others who share their particular condition. These patients deserve our encouragement and support. They do not deserve to be billed for procedures that their insurers would cover if they were not in a clinical trial.

The proposal before your committee does not ask insurance companies to cover more than they should expect to pay. It would only require that insurance companies cover standard of care treatment for patients who are enrolled in clinical trials as they would for patients who are not enrolled in clinical trials. The language in the bill states that routine patient care is care "that would otherwise be covered if such services were not rendered pursuant to a clinical trial." Insurers vary significantly in how they cover these costs. This legislation would create a more rational outcome for patients.

Under President Clinton, Medicare made the common sense change to cover routine patient care costs for clinical trial patients. The Medicare coverage is, sensibly, not limited by disease. I believe that the Connecticut General Assembly should make this same change.

The recently passed landmark Affordable Care Act requires coverage of routine patient care costs but only in trials for cancer or other life-threatening diseases. It then provides an extraordinarily narrow definition for 'life-threatening' which does not include the majority of chronic and disabling diseases. This is in conflict with the thoughtful policy developed by the Centers for Medicare & Medicaid Services. While I am also urging our Congressional delegation to take the lead in proposing legislation to expand the scope of coverage under federal law, I believe that state action this year is necessary and desirable.

In addition, section 15 of this bill would allow greater use of drugs off-label. There are a number of drugs that have been shown to be effective against rarer diseases in small trials, but which will never be approved for those diseases because there is no way to do the large multi-center trials. These are drugs with known safety profiles that are already approved for specific diseases. Our state currently requires coverage for off-label use of cancer drugs; it is illogical to deny this coverage for other diseases.

S.B. No. 18 AN ACT CONCERNING APPEALS OF HEALTH INSURANCE BENEFITS DENIALS, would create greater equity for patients who are denied services from managed care organizations, health insurers, or utilization review companies ("insurers"). Currently, when one of these organizations denies coverage, the burden of proof in the appeals process is on the provider and the patient to prove that the service or drug, or device is medically necessary. One of the problems with this system is that only the insurer knows why the claim was denied. In general, the burden of proof in any case should be placed on the party who has the information. In this case that party is the insurer. SB 18 would create an assumption that medical treatments, drugs, and devices that are ordered by a licensed provider are medically necessary. It places the burden of proof in its rightful place, on the insurer that is denying coverage.

In addition, the insurers are not always forthcoming with the record in the case; access to the record would offer the patient and the provider critical information as to how the decision to deny coverage was formulated. This bill would require that the insurer provide this information to the patient and provider; the patient and physician should not be left guessing as to the reasons for denial. This legislation would allow them a chance to present the counter-argument with access to all the appropriate information; it is simply a matter of fairness.

In cases where the denial of service is in regard to a prescription drug, the bill would require that the insurer provide the patient with the drug for the course of

the appeal. This protects the patient by giving him or her access to needed medication and encourages the insurer to resolve the case quickly.

Again, thank you for raising these important bills which would assist patients in our healthcare system.