

Congress and Congressional Process

A Positive Force for Patients & Research Advancement

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Peggy Tighe, JD, Principal Powers law firm

- ▶ Deciphers and interprets highly complex healthcare matters and translates them into action.
- ▶ Teams with patient groups and provider organizations to develop persuasive policy arguments and strategies to influence Congress and relevant agencies, creating change to protect and support providers and the patients they serve.
- ▶ Serves as Legislative Counsel to the American Society of Transplant Surgeons (ASTS). Nearly 30 years of government relations experience.



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Agenda

- ▶ Living Donor Protection Act (LDPA)
- ▶ Dialysis Patients Demonstration Act (DPDA)
- ▶ Immunosuppressant legislation



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Living Donor Protection Act

BEST ATMOSPHERE IN A DECADE TO ADVANCE LDPA

- ▶ Active and engaged Champions (Reps. Nadler, Herrera-Beutler & Senators Gillibrand and Cotton)
- ▶ Department of Labor opinion letter is Game-Changing
- ▶ Vocal and active commitment from Administration on Transplant and living donation.
- ▶ Active, trusted allies also seeking LDPA co-sponsors: AAKP, NKF, & AST.



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Living Donor Protection Act

LDPA SUMMARY

Promotes organ donation and protect living organ donors in three ways...

1. Prohibits life, disability, and long term care insurance companies from denying or limiting coverage and from charging higher premiums for living organ donors;
2. Clarifies that living organ donors may use Family Medical Leave Act (FMLA) time to recover from the surgeries and procedures involved in their donation; and
3. Directs HHS to update their materials on live organ donation to reflect these new protections and encourage more individuals to consider donating an organ.



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Living Donor Protection Act

LEGISLATIVE STATUS

H.R. 1224: Reps. Nadler (D-NY) & Herrera Beutler (R-WA)

- ▶ 53 cosponsors

S. 511: Senators Kirsten Gillibrand (D-NY) & Tom Cotton (R-AR)

- ▶ Boozman, John (R-AR)
- ▶ Coons, Christopher A. (D-DE)
- ▶ Brown, Sherrod (D-OH)
- ▶ Cramer, Kevin (R-ND)
- ▶ Blumenthal, Richard (D-CT)
- ▶ King, Angus S., Jr. (I-ME)
- ▶ Markey, Edward J. (D-MA)
- ▶ Rosen, Jacky (D-NV)



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Living Donor Protection Act

DEPARTMENT OF LABOR OPINION IS GAME-CHANGER

Hurdles for passage...

- ▶ LEGISLATIVE FEAR of “opening up” FMLA to other changes
DOL OPINION means: Donors can already use FMLA, so any legislation does not have to “open up” FMLA to any other changes to FMLA.
- ▶ COST OF NEW MANDATE on employers to provide leave
DOL OPINION means: Employers are already required to do this, so merely codifying the DOL opinion should NOT bring new costs.
- ▶ 5 committees of jurisdiction, several with FMLA jurisdiction
DOL OPINION means: Committees are far more likely to not see this is a dramatic new change that needs Congressional review.



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Dialysis Patients Demonstration Act

LEGISLATIVE STATUS

- ▶ Most recent DRAFT released in September 2019, no Congressional activity (hearings, floor action) to advance.
- ▶ DPDA has yet to be introduced. Sponsors actively seeking to reintroduce similar legislation in the 116th Congress.
- ▶ Last session the bill was led by Reps. Smith (R-MO) and Blumenauer (D-OR) in the House and Sens. Young (R-IN) and Nelson (D-FL) in the Senate. Young and Nelson both lost their reelections.
- ▶ Two key, Democrat Senators who were previous sponsors declined to co-sponsor this session – Shaheen (D-NH) and Bennet (D-CO).



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Dialysis Patients Demonstration Act

OVERVIEW

- ▶ Introduced as the Dialysis Patient Access To Integrated-care, Empowerment, Nephrologists, Treatment, and Services (PATIENTS) Demonstration Act of 2017. Referred to as DPDA.
- ▶ Would establish a new demonstration program under which an unlimited number of Organizations created by large dialysis organizations would be paid on the basis of Medicare Advantage capitated rates for all Medicare services (including transplantation) provided to ESRD patients who regularly receive dialysis from them.



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Dialysis Patients Demonstration Act

ASTS MAIN CONCERNS

- ▶ Make Dialysis Providers Responsible for Transplant
- ▶ Dis-incentivize Transplant Via Strong Financial Incentives
- ▶ Severely Limit Beneficiary Choice
- ▶ Contradict and Preempt Existing Government Efforts to Coordinate Care for ESRD Patients



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Immunosuppressant Drug Coverage

OVERVIEW

- ▶ In general, the legislation sought to extend the entitlement to prescription drugs used in immunosuppressive therapy furnished to an individual who receives a kidney transplant for which payment is made under Medicare (past the 36 months under current law).



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Immunosuppressant Drug Coverage

TIMELINE

- ▶ First introduced by Senator DeWine (R-OH) – 2003
- ▶ Reintroduced in 114th session (2015-2016), Dr. Burgess (R-TX) & Kind (D-WI) – September 2016
- ▶ Most active time for legislation, staff worked with CMS and CBO to advance the bill but were repeatedly thwarted.
- ▶ NOT reintroduced in 115th session (2017-2018).
- ▶ New efforts to advance immunosuppressant drug coverage in 2018-19.



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Immunosuppressant Drug Coverage

HURDLES

- ▶ Legislation stalled because...
 - ▶ CMS has not provided the information on which Medicare ESRD patients who received a transplant have exhausted the 36 months of coverage.
 - ▶ CBO therefore can not accurately determine the cost of extending such coverage past the 36 months.
 - ▶ CBO does not score prevention as a legislative savings. The difference between dialysis costs and transplant costs over time is not something they have considered in scoring legislation, but for one example.



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Immunosuppressant Drug Coverage

OPPORTUNITIES

- ▶ *The Administration has evidenced a strong commitment to paving the way for legislative action on the immunosuppressant drug coverage bill.*
- ▶ *On May, 10, 2019, the Assistant Secretary for Planning and Evaluation (ASPE) study released a study determining that such a bill would be a cost SAVER. We welcome the news but are skeptical of the methodology, and are reviewing it more closely.*
- ▶ *We understand that the CMS-Office of the Actuary (OACT) is also planning on releasing an analysis that would determine that such legislation would be a cost saver.*



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