

Memorandum


Conclude Relaxation of Data Submission Requirements for Follow-up Forms

OPTN Executive Committee

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Conclude Relaxation of Data Submission Requirements for Follow-up Forms

Affected Policies:

18.1.B: Timely Submission of Certain Data

18.2: Timely Collection of Data

18.5.A: Reporting Requirements after Living Kidney Donation

18.5.B: Reporting Requirements after Living Liver Donation

Sponsoring Committee:

Executive

Executive Committee Meeting Date:

March 1, 2021

Executive Summary

The OPTN Executive Committee implemented four emergency actions in March and April 2020 to address the effects of the COVID-19 pandemic on the transplant community. Following the emergency actions, the changes were published for public comment, and the OPTN Board of Directors (Board) endorsed the policy changes to remain in place until such time as the Executive Committee deemed they were no longer necessary. At that time, the Board directed the Executive Committee, Membership and Professional Standards Committee (MPSC) and staff to work together with programs who may be suffering variable effects from the pandemic to collect all data feasible. The Executive Committee has reviewed monthly reports on the usage of the policy, as well as data on the effects of COVID-19 on transplantation, at each of its meetings to consider whether it might be appropriate to end each policy.

Action 2, *Relax Data Submission Requirements for Follow-up Forms*, was a change to suspend requirements for data collection and submission for policy required living donor follow-up (LDF), organ specific transplant recipient follow-up (TRF), and recipient malignancy (PTM) data collection instruments and change the reporting timeline for recipient graft failure and death on TRF forms from 14 days to 30 days.

- Transplant Recipient Follow-up (TRF): Data collected at six months, one year, two year, and annually thereafter post-transplant until death or graft failure. Additional interim forms are submitted at graft failure and death events. Information collected includes graft/patient status with dates, immunosuppression at one year, other outcomes including general (acute rejection episodes) and organ-specific (creatinine, EF, incidence of BOS, etc.), and quality of life measures like employment and functional status.
- Living Donor Follow-up (LDF): Data collected at six months, one year, and two years post-donation. Includes information on living donor patient status, quality of life measures such as employment, physical capacity, and functional status, organ-specific lab values (creatinine, bilirubin, etc.), organ-specific complications (diabetes, high blood pressure, etc.), and other complications such as readmission, native organ failure, etc.

- Post-Transplant Malignancy (PTM): Form is generated when a post-transplant malignancy is reported on a transplant recipient follow-up (TRF) form. Includes details on tumor location, tumor type, and date of diagnosis.

The Executive Committee has encouraged members to access these forms and submit data retrospectively as circumstances in their local area allowed, accounting for increased COVID-19 exposure risks to transplant recipients and living donors, or diminished data entry capacity due to staff constraints in the midst of the COVID-19 crisis. At this time, national COVID-19 diagnosis numbers are declining and the data submission rates are increasing, and it may be appropriate to put in place a plan for reporting certain data that was postponed during the period of reduced data reporting.

The Executive Committee will consider whether to:

1. End data amnesty by sunseting the policy changes associated with Action 2, *Relax Data Submission Requirements for Follow-up Forms*
2. Require members to complete some or all of the TRF, PTM, and LDF forms that would have been due during the period of amnesty

Sunset Amnesty

The overall number of new cases of COVID-19 in the United States is trending downward according to the latest CDC reports, with hope that the downward trend will continue as more people are vaccinated. As of February 14, 2021, more than 14 million Americans have received both doses of a COVID-19 vaccine.¹

Figure 1: Daily Trends in Number of COVID-19 Cases in the United States Reported to the CDC²



Transplants are continuing at levels similar to pre-pandemic despite the early dip, demonstrating that the donation and transplant community is continuing to adapt to this rapid change.

¹ Centers for Disease Control and Prevention, COVID Data Tracker, COVID-19 Vaccinations in the United States. <https://covid.cdc.gov/covid-data-tracker/#vaccinations> (Accessed February 15, 2021).

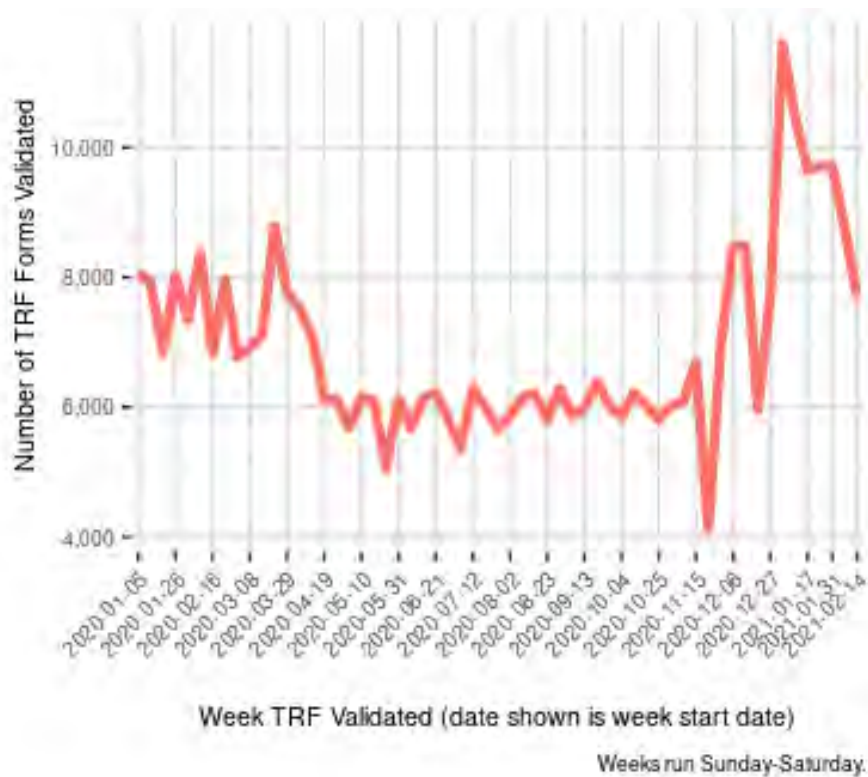
² Centers for Disease Control and Prevention, COVID Data Tracker, Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory. https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases. (Accessed February 15, 2021).

Figure 2: Year-to-Date Transplants for 2019, 2020 and 2021³



Additionally, the numbers of total forms in amnesty status are dropping, with transplant hospitals completing both new forms and those previously in amnesty status, which may indicate that members are having less difficulty with data collection and reporting for these data instruments.

Figure 3: Number of TRFs Validated 1/5/2020-2/20/2021, by Week Validated⁴

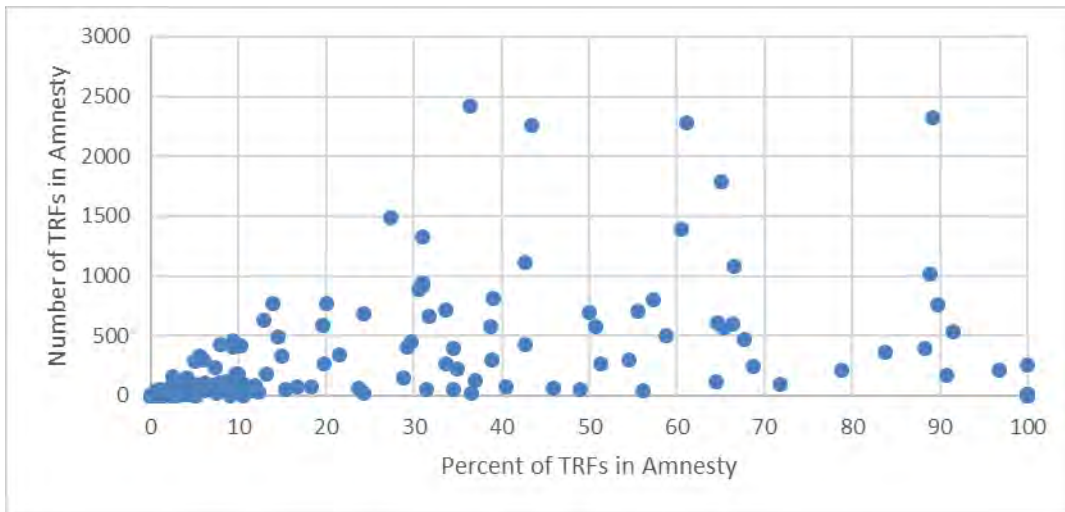


The number and percentage of total forms (TRF, LDF, and PTM) in amnesty as of 2/21/2021 varies widely, from 0 to 2,434 (median 22) forms and 0 to 100% (median 3.8%) by transplant hospital.

³ UNOS, COVID-19 and Solid Organ Transplant. <https://unos.org/covid/> (Accessed February 15, 2021).

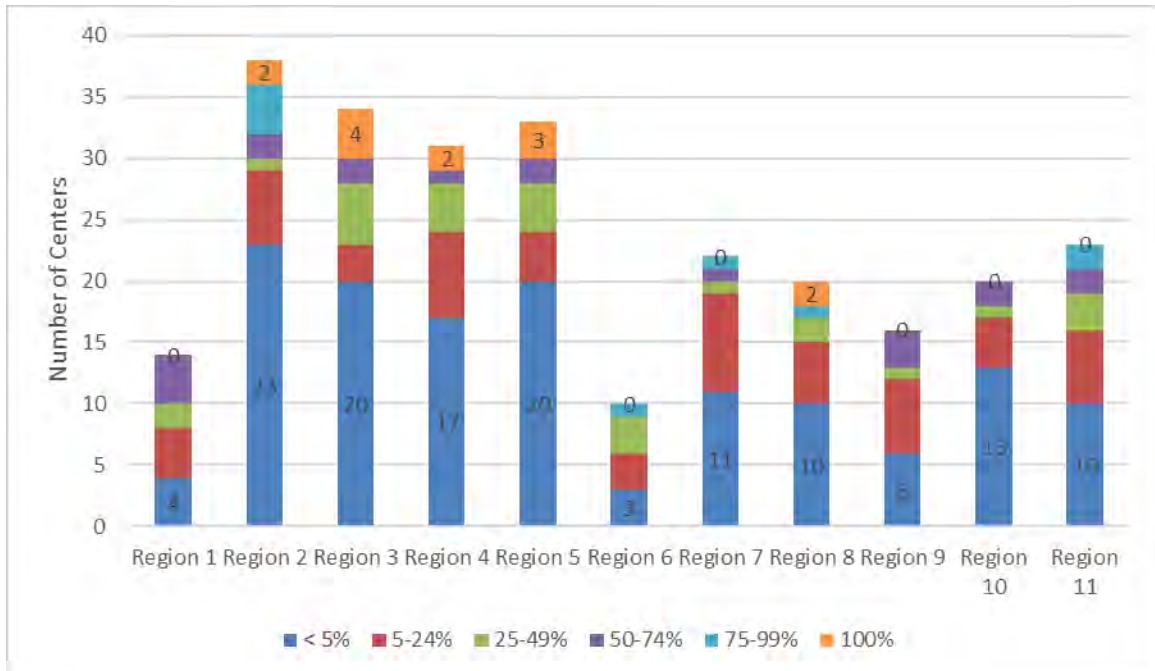
⁴ OPTN data. February 21, 2021.

Figure 4: Number and Percent of TRF Forms in Amnesty as of 2/21/21, by Center⁵



Most transplant hospitals have a small number and small percentage of their TRF forms in amnesty status. Thirteen transplant hospitals have 100% of their TRF forms in amnesty, but those are not the hospitals with the highest numbers of forms in amnesty.⁶ Figure 4 displays the number and percentage of TRF forms in amnesty by hospital as of February 21, 2021. As seen in Figure 5, the regional trends are consistent with the national trends, with most centers having less than 5% of their TRF forms in amnesty and 8 of 11 regions having at least one hospital with more than 74% of their TRF forms in amnesty.

Figure 5: Number of Centers with Specified Percent of TRF Forms in Amnesty on 2/21/2021⁷



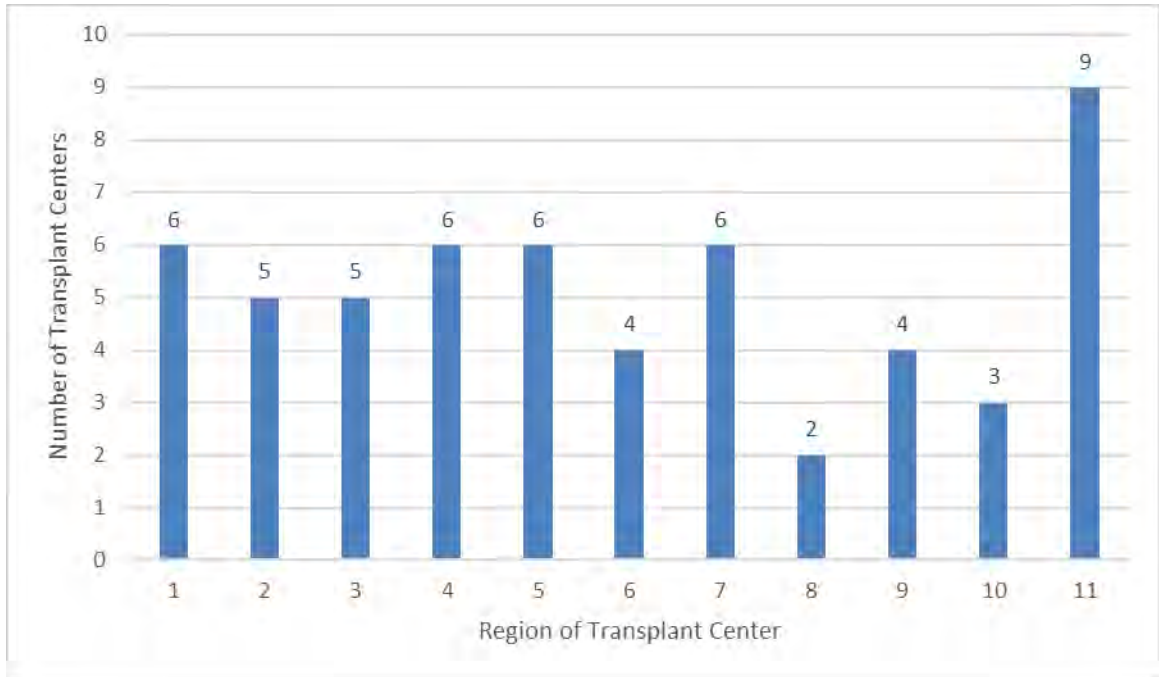
⁵ Ibid.

⁶ Ibid.

⁷ Ibid.

There are 56 hospitals with more than 250 TRF forms in amnesty, nationally, with all regions represented (Figure 6).

Figure 6: Number of Transplant Hospitals with More than 250 TRF Forms in Amnesty as of 2/21/21, by Region⁸



Based on the trends toward fewer COVID-19 cases, improved data reporting and increased vaccinations, the Executive Committee may want to consider having the TRF, LDF and PTM amnesty policy sunset effective April 1, 2021, giving members 30 days notice. The MPSC, Data Advisory Committee (DAC), Transplant Administrators Committee (TAC) and Transplant Coordinators (TCC) agree that this would be appropriate. With follow up collected for recipients and living donors on an annual basis, the longer the amnesty policy remains in effect, the larger the gap in follow up for patients will be.

Retrospective Data Collection

Requiring retrospective completion of forms that were in amnesty would provide greater data for evaluation of patient outcomes, policy effectiveness and living donor safety, as well as the impact of COVID-19 on transplantation. In particular, certain data reported on the TRF are essential for the SRTR’s program specific reports (PSR), which are a widely used metric of hospital performance. However, there may be challenges if certain clinical information was not collected at the time the form would normally have been due, and fields may be largely filled in with responses of “unknown” or “not done,” which would be less useful for future evaluation. This is especially likely for values that could not be accurately collected through a telehealth visit, such as height and weight or laboratory values, since many hospitals used telehealth to continue care through the pandemic. In addition, members may have planned their staffing with the assumption that they would not need to retrospectively report the data on these forms. If the Executive Committee chooses to sunset the amnesty policy, then it may also consider how much retrospective form completion to require. The Executive Committee can balance the value of the data that would be collected and the additional member burden. Five options that were considered or

⁸ Ibid.

supported by committees are listed. The first two include at least some portion of all forms that were due, and are the options the Executive Committee will consider.

1. Require submission of all forms that were due during the amnesty period
2. Require submission of only the patient status, graft status, and associated dates on all TRF forms that were due during the amnesty period. Also require retrospective submission of LDF and PTM forms.

Options 3-5 were also considered and supported to some degree by other committees, but do not include completing a least some data on each form, and therefore these options would not meet the requirements of the OPTN Final Rule for transplant hospitals to submit information regarding transplant recipients and organ donors to the OPTN in accordance with the prescribed schedule.⁹

3. Require complete submission of all fields on TRF and PTM forms from the first 3 years following transplant that were due during the amnesty period. Do not require retrospective submission of LDF or later TRF forms.
4. Require submission of only the patient status, graft status, and associated dates, on only the TRF forms from the first 3 years following transplant that were due during the amnesty period. Do not require retrospective submission of LDF or PTM forms.
5. Do not require retrospective data submission for any forms that were due during the amnesty period.

More information about each option is included below in *Table 1*.

⁹ See 42 C.F.R. 121.11(b)(4), requiring that a "transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN...and the Secretary information regarding transplantation candidates, transplant recipients, donors of organs...".

Table 1: Retrospective Data Collection Options Considered by OPTN Committees

		1: Complete Data Collection	2: Outcomes Focus	3: Recent Forms Focus	4. PSR Focus	5. No Data Collection
TRF Details	Which forms	All forms	All forms	6m, 1y, 2y, 3y follow up forms	6m, 1y, 2y, 3y follow up forms	None
	Which data fields	All data	Partial data *Patient Status/Date *Graft Status/Date	All data	Partial data *Patient Status/Date *Graft Status/Date	N/A
	# Forms as of 2/21/21 ¹⁰	48,261	48,261	17,645*	17,645	0
PTM Details	Which forms	All forms	All forms	Tied to 6m, 1y, 2y, 3y follow up forms	None	None
	# Forms as of 2/21/21 ¹¹	499	499	129	0	0
LDF Details	Which forms	All forms	All forms	None	None	None
	# Forms as of 2/21/21 ¹²	2,551	2,551	0	0	0
Committee support ¹³	DAC - Option 1	DAC				
	TAC – Option 3 or 4 Believed that most transplant recipient data could be reported, but living donor information was less likely to be available, and not all patients have been coming in on time for followup			TAC	TAC	
	TCC - Option 3 Understand the value of having the data, but concerned about ability to collect all information given use of telehealth visits			TCC		
	MPSC - Option 5 Concerned about adding this requirement when it was not evident that it would be required when amnesty policies were enacted					MPSC
SRTR	Performance monitoring limitations due to incomplete post-transplant outcomes data - affecting PSRs	None	None	None	SRTR Recommendation	Impacted
Policy Monitoring	Limitations on monitoring of pancreas graft failure definition change	No impact	Impacted	Impacted	Impacted	Impacted
	Limitations on monitoring of CLAD data collection (lung)	No impact	Impacted	Impacted	Impacted	Impacted

¹⁰ OPTN data. February 21, 2021.

¹¹ Ibid.

¹² Ibid.

¹³ The Living Donor Committee was supportive of aligning the requirements for recipients and donors.

		1: Complete Data Collection	2: Outcomes Focus	3: Recent Forms Focus	4. PSR Focus	5. No Data Collection
TRF Research/Analysis Limitations	Information will still be incomplete if recipients were not seen during the amnesty period	Potential impact	Potential impact	Potential impact	Potential impact	N/A
	Incomplete data on patient and graft survival outcomes until next follow-up forms come due (up to a year)	No impact	No impact	Impact on data more than 3 years post-transplant	Impact on data more than 3 years post-transplant	Impacted
	Incomplete data on complications such as acute rejection, hospitalizations, and post-transplant malignancies post-transplant. Used in research and formal reports such as HOPE Act monitoring.	No impact	Impacted	Impact on data more than 3 years post-transplant	Impacted	Impacted
	Lack of data on zip code of residence during this period limits ability to fully understand impact of pandemic on transplant recipients.	No impact	Impacted	Impact on data more than 3 years post-transplant	Impacted	Impacted
PTM Research/Analysis Limitations	Incomplete data on post-transplant malignancies. Used in research and some formal reports such as HOPE Act monitoring.	No impact	No impact	Impact on data more than 3 years post-transplant	Impacted	Impacted
LDF Research/Analysis Limitations	Information will still be incomplete if living donors were not seen during the amnesty period	Potential impact	Potential impact	N/A	N/A	N/A
	Data on certain living donor complications will be incomplete, and ability to understand impact of pandemic on those living donor cases limited.	No impact	No impact	Impacted	Impacted	Impact
Implementation plan	Set forms to Expected with new Due Date (puts form in queue for forms that need to be validated)	All forms	LDF and PTM	6m, 1y, 2y, 3y TRFs and PTMs	None	None
	Forms remain in Amnesty: Separate reporting tool(s) assist member in finding forms to be completed	None	TRF	TRF and PTM forms years 4 and beyond, and recipient death and graft failure TRF forms. All LDF.	All forms	All forms

Retrospective Data Submission Deadline

If the Executive Committee chooses to end amnesty and require retrospective form submission, the next decision is what deadline to set for the completion of those forms. Options are presented below.

Table 2: Retrospective Data Submission Timeline Options

Retrospective Data Submission Deadline	Time After Amnesty End	Committee Support	SRTR/Performance Monitoring Limitations ¹⁴
April 30	29 days	DAC (phase 1) DAC members wanted to prioritize the forms used in PSRs (TRFs from 1 st three years) for the upcoming deadline. They supported giving a longer period to complete the remaining forms.	Information will be complete in time for incorporation in the July 2021 PSRs and those after
July 1	90 days	TCC believed 90 days would be sufficient for most transplant hospitals to complete retrospective collection and entry if it was limited to patient and graft status and only the first 3 years of forms.	Complete in time for October 2021 draft PSRs
August 30	6 months	DAC (phase 2) DAC members thought it was reasonable to allow more time for the LDF and PTM forms, and the TRFs from years 4 onward, and tie that deadline to the next PSR deadline. TAC was concerned that many data entry staff and staff with previous nursing experience are currently assisting with vaccine deployment, that some areas are still recovering from the second surge, and that there may be a surge of staff vacations as travel restrictions are lifted and staff are able to use accumulated vacation time. They were also concerned that it would require time to schedule patients to come in for lab work if those fields are required.	Complete in time for October 2021 draft PSRs
October 31	8 months	This is the next public PSR deadline after April 30. MPSC preferred to provide as much time as possible for members to catch up, but suggested aligning with the next PSR deadline.	Complete in time for January 2022 PSRs
April 1, 2022	1 year		Complete in time for May 2022 PSRs

The MPSC, DAC, and TCC supported including milestone goals along the way to encourage members not to wait for the deadline to enter data, and allowing flexibility for members who may need more time to submit retrospective data. Based on the suggestions of these groups, additional guidance and reports would be provided to members to encourage submitting oldest forms first, and completing 25%, 50% and 75% of their forms in amnesty at earlier milestones.

¹⁴ PSRs are published publically two times a year, in January and July. Draft PSRs are released only to the OPO or hospital that provided the data, and are released in April and October.

Timely Collection of Living Donor Data

The relaxed data submission policies included suspension of the requirement for living donor recovery hospitals to collect the data reported on the LDF within 60 days of the donation date.¹⁵ Because this requirement related to the timing of the data collection, and it is not possible for a hospital to retrospectively collect within that time period, each option for retrospective data submission includes language excluding the forms that would have been due during the amnesty period from this data collection timing requirement.

Data Submission Project Timing

The DAC provided feedback related to the timing of the implementation of the *Modify Data Submission Policies* project approved by the Board December 3, 2019, and currently awaiting implementation. Implementation of the *Modify Data Submission Policies* project while the data amnesty policies are in place would create significant additional burden each time a member wanted to submit data outside the normal due date, and the DAC would instead prefer to encourage any data entry during this period. DAC requested implementation of these data submission changes on August 1, 2021, assuming any retrospective data collection period ends June 1, 2021 at the latest. DAC requested that programs be given a minimum of 60 days after the end of any retrospective data requirements before the *Modify Data Submission Policies* project be implemented.

Conclusion

The Executive Committee may consider whether to end the *Relax Data Submission Requirements for Follow-up Forms* changes effective April 1, 2021 and put in place requirements for members to retrospectively complete forms.

¹⁵ Briefing to the OPTN Board of Directors, COVID-19 Emergency Policies and Data Collection, OPTN Executive Committee, December 7, 2020. <https://optn.transplant.hrsa.gov/media/4200/covid-19-emergency-policies-and-data-collection.pdf>. (Accessed February 16, 2021).